OVERSIGHT OF THE SMALL BUSINESS INNOVATION RESEARCH AND SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAMS - PART II

HEARING

BEFORE THE

COMMITTEE ON SMALL BUSINESS
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HOUSE OF REPRESENTATIVES

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OVERSIGHT OF THE SMALL BUSINESS INNOVATION RESEARCH AND SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAMS - PART II

WEDNESDAY, JULY 23, 2014

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Committee met, pursuant to call, at 1:00 p.m., in Room 2360, Rayburn House Office Building. Hon. Sam Graves [chairman of the Committee] presiding.

Present: Representatives Graves, Chabot, Coffman, Leutkemeyer, Tipton, Hanna, Huelskamp, Collins, Velázquez, Schrader, Payne, Meng, Barber and McLane Kuster.

Mr. LUETKEMEYER. [Presiding] Okay. We can begin the proceedings here.

I am Congressman Luetkemeyer, sitting in for Congressman Graves this afternoon. And I am glad that we have such a large participation by the Committee today. But we are glad everybody else is here today. And with that, opening statement will begin.

Good afternoon. Thank you all for being here. Today, we are holding the second of two oversight hearings this year to examine the changes made in the National Defense Authorization Act for Fiscal Year 2012 to both the Small Business Innovation Research, or SBIR, and Small Business Technology Transfer, or STTR, Programs. Our first hearing focused on private sector impressions of those changes. Today, we will focus on what the agencies have been doing to implement the modifications we made in 2012 to these programs.

Innovation is the engine that drives our economy. Technological breakthroughs and the entrepreneurship it spurs build our economy by finding state-of-the-art solutions to difficult problems and marketing those new products. This correlation is particularly important in the small business arena. Small businesses tend to be more nimble, responding to market changes more rapidly than their bigger counterparts, and they drive the innovation sector and make us more agile in the global economy.

It is that recognition of the ingenuity of small firms that led Congress to establish the SBIR program in 1982. It is also the recognition that has led to its subsequent reauthorizations, the last of which was signed into law thirty-one months ago.

This program, which sets aside a portion of federal research and development dollars for small businesses, is critical for both the

small firms that use the grants and the federal agencies that seek innovative solutions to the problems they encounter. Whether it is a new software system for tracking contract payments, a new medical device to help with Parkinson's treatment, or a new piece of technology that helps save lives on the battlefield, the SBIR program has consistently delivered results across all agencies.

The primary goals of the most recent and bipartisan legislation were to increase commercialization of SBIR-funded research, to promote greater participation from a wider array of small businesses, and to increase the end use of the technology developed through the SBIR program by federal agencies.

Today, we have some of the folks most responsible for implementing the changes we wrote into law. I am eager to hear from them on their progress and to hear their impressions of the health of the SBIR and STTR programs.

Again, thank you all for being here, and I yield to Ms. Velázquez for her opening statement.

Ms. VELAZQUEZ. Thank you, Mr. Chairman.

Over the past 30 years, the SBIR and STTR programs have helped fund nearly $40 billion in innovations across a wide range of sectors. New drug therapies, homeland security technologies, and energy saving devices are just a few of the benefits that have resulted from this program. These advances have also brought economic development and job creation, demonstrating the synergy that can form between small businesses and the government. Over the years, these initiatives have been regularly reauthorized by Congress. The last effort resulted in several key changes. Among the most significant was a greater focus on ensuring that these programs produce products that are marketable in the private sector or to government agencies themselves. This is an important goal because the program's intent was never to fund Phase I research over and over, but rather to generate innovations that will fuel the economy and create jobs. With this in mind, I am specifically interested in understanding how agencies are implementing the reauthorization's commercialization provisions, and if they are, in fact, resulting in more successful endeavors. In a similar context, benchmarks have been established to track those companies that continually win Phase I awards without progressing to Phase II. I look forward to examining the agencies' experience with this, especially instances where companies have been made ineligible due to a lack of transitional success.

Another notable change was the significant increase in the agency set-aside for both SBIR and STTR. This has left agencies with hundreds of millions of dollars more to spend on awards. However, some have reported declining applications, which means fewer companies competing for a larger pot of money. Some have suggested that the set-aside was raised too quickly and that the overall competitiveness of the program is now at risk. Today, I hope to get honest feedback from the agencies on this topic.

Finally, there continue to be several ongoing concerns with the program's operation. Agencies' awards remain concentrated in California and Massachusetts, who together receive 35 percent of the total funds from these programs. All together, the top 10 states receive 70 percent. This is often driven in part by agencies awarding

the same companies, year after year, the most awards. It is unclear why new firms are unable to break into this small group of dominant SBIR, STTR awardees. Similarly, the participation of women-owned and minority-owned firms has been declining. Women-owned firms' share of SBIR awards decreased 35 percent in the last 17 years. In the same period, awards for minority-owned firms fell by 70 percent. Overall, according to data on SBIR.gov, last year women-owned firms won 6.4 percent of SBIR awards, while minority-owned firms won just 2.6 percent.

When it comes to geography and demographics, it is important that SBIR and STTR are serving the entire country, and are not becoming a regular source of income for the same companies. At their core, SBIR and STTR are drivers of innovation. In order to be successful, however, we cannot have a program that primarily serves a select few.

During today's hearing, I hope that we can examine these matters, evaluating what is working and what is not is crucial because before we know it, we will be marking up the next reauthorization for this program. Since their establishment, SBIR and STTR have played an important function in driving the development of cutting edge technologies. Given the sizeable investment that we continue to make in them, it is important that we regularly oversee these programs. For that reason, I thank all the witnesses for being here today, and the chairman for calling this hearing.

Thank you, Mr. Chairman. I yield back.

Mr. LUETKEMEYER. Thank you.

Just briefly, if Committee members have an opening statement prepared, I ask that you submit it for the record.

I would also like to take a minute to explain the lighting system in front of you. Green means go. Get to the yellow, you have got about a minute to wrap up. Red means stop. Hopefully, at some point you will stop. If not, well, we have got a big gavel here that says "stop, stop, stop." But be respectful of everybody else, so get your points in and move on.

With that, let me begin the introductions. Our first witness is Javier Saade, Associate Administrator for the Office of Investment and Innovation at the SBA. As part of the SBA senior leadership team, he leads the agency's SBIR and STTR programs, as well as the Small Business Investment Company. He came to SBA with 20 years of global general management, principal investing, strategic consulting, and entrepreneur experience.

Thank you for being here, and you can begin your testimony for five minutes, Mr. Saade.

STATEMENTS OF JAVIER SAADE, ASSOCIATE ADMINISTRATOR, OFFICE OF INVESTMENT AND INNOVATION, UNITED STATES SMALL BUSINESS ADMINISTRATION; MARIE MAK, ACTING DIRECTOR, GOVERNMENT ACCOUNTABILITY OFFICE, ACQUISITION AND SOURCING MANAGEMENT TEAM; ANDRE GUDGER, DIRECTOR, OFFICE OF SMALL BUSINESS PROGRAMS, OFFICE OF THE UNDER SECRETARY OF DEFENSE, DEPARTMENT OF DEFENSE; MATTHEW PORTNOY, DIRECTOR, DIVISION OF SPECIAL PROGRAMS, PROGRAM MANAGER, NIH SBIR/STTR, NATIONAL INSTITUTES OF HEALTH

STATEMENT OF JAVIER SAADE

Mr. SAADE. Thank you, Chairman, Ranking Member Velázquez, distinguished Members of the Committee. Thank you for inviting me here today to discuss the Small Business Innovation Research and Small Business Technology Transfer programs.

I would like to begin with an example. Biogen, now known as Biogen Idec, used early SBIR funding to develop breakthroughs in cancer drugs, such as Rituxan, now the therapy of choice for Non-Hodgkin's Lymphoma, as well as some times of leukemia and arthritis. Biogen's drugs have saved and improved the lives of millions around the world. It is one company alone. It is worth $80 billion today. It was created by this only one company. It has more than doubled. The American taxpayers have invested in these programs since inception. To me, the SBIR program is personal because my dad, Jose, has been in remission for six years and owes his life to Rituxan, literally.

The SBIR and STTR programs do more than just provide grants and contracts. These programs stimulate the STEM-driven economy, as well as support people considering academic careers in a wide range of STEM fields. This is a critical pillar of over national competitiveness. The 11 agencies that participate in the programs, two of which are here today, have awarded over 145,000 grants totaling about $38 billion to American small businesses. In 2012, the SBIR and STTR programs provided about $2.5 billion directly into the hands of small businesses nationwide, and nearly a quarter of that money was awarded to women-owned, minority-owned, or HUBZone located small businesses. The SBA's role in both of these programs is to provide programmatic and policy oversight on these programs. SBIR works very closely with the agency program managers and external stakeholders to ensure that the intent of congress is carried on in the operation of these programs. It must be noted that while there is only one SBIR program, it is operated 11 different ways, depending on the focus of its agency's missions, directives, and goals.

Thanks to this Committee, the SBIR and STTR programs as you noted were reauthorized on January 1, 2012. Annually, GAO conducts a series of reviews. At SBA, we take all these reviews very seriously. To address the recommendations of GAO, our agency has had ongoing discussions with agency program managers. Delegations from around the world, including Finland, Japan, Italy, U.K., and India, among others, have visited our office to learn about these truly world-class innovation programs. These programs, in fact, make up the world's largest seed fund.

While we are still the undisputed world leader in innovation, we are not alone, and many countries are making serious commitments of their own to their own innovation efforts. As we speak, today, as an example, China is investing billions of dollars and millions of engineering hours in its own space program. We need to continue to invest in our future as other countries continue to catch up.

To maximize the commercialization and worth of taxpayer investment, SBA is launching a commercialization database. This database will allow the private sector to easily search SBIR and STTR funded innovations and increase investment in the high growth small businesses.

IRobot, another success story. This company created the Roomba vacuum cleaner, now a household name. This company received SBIR funding from DoD to develop robots that conduct dangerous missions, such as mine detection and explosive disposal, keeping our soldiers out of harm's way. What is interesting is that iRobot pivoted its military design technologies towards mainstream consumer needs and now has sales of over half a billion dollars and employs 500 people. This is truly a remarkable example of an entrepreneur spotting a dual use for a technology developed for our nation's defense needs.

SBIR and STTR are critical components of America's economic growth and are also key to advancing next generation science, engineering, and technology. Job creation is a national goal. Job creation, plus innovative research, leads to global competitiveness. As SBA's associated administrator, I will continue to work closely with our sister agencies to make sure that the programs are top priorities across the federal government. I will hold agencies responsible for the allocations required by statute, and I will continue to work with all of you to improve these programs. They are true gems, and we must make sure that our small businesses know about these great opportunities. Thank you.

Mr. LUETKEMEYER. Thank you, sir.

Next, we have Marie Mak. Is that right? The Acting Director in the Government Accountability Office of the Acquisition and Sourcing Management Team. In her position, she leads a diverse portfolio addressing contracting issues, including ongoing reviews related to the Department of Defense's service contract limitations, subcontracting under construction contracts, and management of the international space station. She has been the GAO since 2002. We appreciate your being here.

You have five minutes. Thank you very much.

STATEMENT OF MARIE MAK

Ms. MAK. Good afternoon, Chairman Luetkemeyer, Ranking Member Velázquez, and Members of the Committee. Thank you for inviting me here today to discuss GAO's work on DoD's efforts to transition technologies developed through the SBIR program. My statement today will primarily focus on our SBIR report issued in December of last year. We reviewed the tools the military services use to support technology transition and assess the extent SBIR technologies were successfully transitioning to military users.

There are two key topics from this review that I would like to highlight today. First, while DoD's SBIR program has developed technologies that support military users, comprehensive data on transition outcomes are lacking. Second, DoD has not established a plan for how and when it would be able to meet the 2012 congressional mandate to begin reporting the number of SBIR projects that transition. Let me start by saying that over the years, Congress and DoD have increasingly recognized the value of the SBIR program and have taken steps to improve opportunities for transitioning SBIR developed technologies to military users. For example, the military services currently provide SBIR awardees additional funding to move certain projects closer to transition. They also have facilitators who work directly with small businesses and acquisition programs to foster transition commitments and support the progress of projects.

As a result, there have been notable successes where SBIR technologies have transitioned to weapon systems or to direct use by the warfighter. These transition stories cover a broad range of technologies and products, but they are collected only on an ad hoc basis through voluntary submissions by program officials and small businesses.

Comprehensive data about the nature and full extent of technology transition that is actually occurring is lacking, which is my first key topic I want to highlight today. DoD and the military services use two data systems to varying degrees to identify transition results—the company commercialization reports and the federal procurement data system next generation. However, these systems have significant gaps in coverage and data reliability concerns that limit their use for capturing transition data. For example, while these systems do provide high level commercialization information such as some investments and contracting information associated with SBIR contracts, they were not intended or even designed for capturing transition outcomes or detailed information on acquisition programs or fielded weapon systems. Without comprehensive data, we found that DoD is unable to meet the fiscal year 2012 congressional mandate to report the number and percentage of SBIR projects that transition to acquisition programs or fielded systems.

At the time of our report, the Department was still assessment options for how to obtain better data and had not yet established a plan for how and when it would be able to do so, which is my second topic today. In our report, we recommended that DoD develop a plan to move forward with timelines and appropriate steps to address the data issues. We recognize there may be resource and technical challenges to collecting more comprehensive data, but we identified opportunities available for DoD to improve its tracking and reporting of transition outcomes. We found, for example, that the Navy has a potential best practice for assessing and documenting technology transition outcomes in its Future Naval Capabilities Program, a technology development effort separate from SBIR that the Department may be able to use on a broader scale. There may also be opportunities to use existing reporting mechanisms from acquisition programs. Furthermore, DoD could consider greater use of contracting provisions to require contractors to report on SBIR transition activities.

Ultimately, however, the key to obtaining better data may require closer collaboration between SBIR and the acquisition communities within DoD. Incremental improvements may be possible to modify existing data systems and increasing SBIR program managers' capacity to track projects. But greater insights into transition outcomes and the benefits the technologies provide to military users may be better achieved with further involvement with the acquisition program managers, the users of those technologies. In an environment of declining budgets, it is important that data on technology transition outcomes for SBIR projects be improved for DoD to ensure that the right technologies transition to the right users in an economical and timely way.

Chairman, Ranking Member, and Members of the Committee, this completes my prepared remarks. I would be pleased to answer any questions you may have.

Mr. LUETKEMEYER. Thank you, Director Mak.

With that, our next witness is Andre Gudger, Director of the Department of Defense Office of Small Business Programs. He serves as the principal advisor to the Secretary of Defense on small business-related matters. Mr. Gudger's career expands over 17 years in the defense, intelligence, and investment banking industries. He has been in his current position since 2011.

Thank you for being here with us today. You have five minutes.

STATEMENT OF ANDRE GUDGER

Mr. GUDGER. Thank you, Chairman Graves, Congressman Luetkemeyer, and Ranking Member Velázquez.

This is a great opportunity for us to talk about progress the Department of Defense has made, and since the reauthorization which has 41 provisions, which 34 of those applied directly to the Department of Defense, we have successfully implemented all 34 of those as of today. And that is a great news story for us, because we have noticed an uptick in the amount of small businesses participating in DoD programs. Never has the playing field been this level before, and we see that our number of new entrants has increased. We have 21 percent of every single solicitation that we put out in SBIR and STTR is a new entrant to the Department of Defense, which means every five solicitations we turn over our industrial base each time, and that shows our commitment to reaching out to states that do not participate or had not traditionally participated at a high level. Reaching out to them and getting them included in DoD acquisitions, and also looking at the greatness that we have with companies that are currently doing business with the Department of Defense.

When we look at the numbers, which we have been collecting since 1983, we have been able to summarize that for every dollar invested in Phase I, $2 are invested at the Phase III level, commercialization. Out of every four awards we make in SBIR, Phase I, one of those awards go to a Phase III commercialization, which is great news. When we look at our minority participation and our women-owned participation, in 2012, 14 percent of our SBIR awards went to women-owned small businesses. In 2012, 6 percent of our SBIR awards went to minority companies. Those are both higher than the congressionally mandated goal of 5 percent. So it

is a high bid for us. It is traditionally thought of that service-based professional services is a leading place for small business to do business at the Department of Defense, but this data shows us that small, minority, women-owned companies do innovate, and if we open the door and show them the kind of things the Department has as a priority, that they will participate in our solicitations and be very successful.

So when I look at the overall health of the DoD SBIR program, we have seen tremendous improvement. We have taken a quantum leap in the right direction. Not only have we accelerated payments to small businesses, but we do targeted outreach now. We are on Facebook. We are on Twitter. We talk the talk that innovative companies talk now, and that has led to great outcomes for us. We have an initiative that will lead to better outcomes in our department. We do not talk just innovation technology; we talk innovation of our people. And that is the reason why we made investments and improvements of our acquisition workforce, particularly our small business professionals.

So with that being said, I would like to give back some time and answer any questions that you have for me. Thank you.

Mr. LUETKEMEYER. Thank you, sir.

Next up is Dr. Matthew Portnoy, director of the Division of Special Programs at the Office of Extramural Programs as well as the National Institutes of Health, SBIR/STTR program coordinator. Most recently, Dr. Portnoy worked at the National Institute of General Medical Sciences, both as a program director and as that program's SBIR/STTR program coordinator. Dr. Portnoy came to NIH in 2001 as an intramural postdoctoral fellow at the National Human Genome Research Institute.

Thank you for being here. You may begin your five minutes, sir.

STATEMENT OF MATTHEW PORTNOY

Mr. PORTNOY. Thank you. Good afternoon, Chairman Luetkemeyer, Ranking Member Velázquez, Members of the Committee. I am Dr. Matt Portnoy, the director for the Division of Special Programs within the Office of the Director at the National Institutes of Health, and the coordinator for the SBIR/STTR programs at NIH. Thank you for the opportunity to discuss the SBIR and STTR programs and our progress on the implementation of the Reauthorization Act.

NIH is one of the largest funders of the program and the largest federal supporter of biomedical research. The SBIR and STTR programs continue to be critical to feeding the innovation pipelines that promises to deliver the medical advances of tomorrow and have complemented NIH's mission to advice science while bringing new health care solutions to the public.

Examples of the types of research that NIH supports through the SBIR and STTR programs include drug discovery, drug and pharmaceutical development, medical devices, biosensors, nanotechnologies, and many other technologies that enhance health, lengthen life, and reduce illness and disability.

Research-initiated ideas are the cornerstone of the NIH research portfolio, including projects supported by the SBIR and STTR programs. I am proud to say that the implementation of many changes

included in the Reauthorization Act are completed or nearly completed at NIH. In accordance with the law, the NIH increased its set-aside for SBIR and STTR to 2.8 and 0.4 percent, respectively, of its extramural budget in Fiscal Year 2014. Since the reauthorization, the overall budget for the programs has increased from $680 million in Fiscal Year 2011 before the reauthorization, to the current Fiscal Year 2014 set-aside of $758 million. Throughout, NIH and HHS have continued to meet and exceed the required set-asides each year as stated in recent GAO reports. We have bolstered and diversified our average efforts and are partnering with the NIH Institutional Development Award (IDeA) program as required to reach underserved small businesses in IDeA states, increasing outreach to women-owned and small disadvantaged businesses, collaborating with more state-based economic development centers to deliver a regular series of webinars and in-person outreach, educating entrepreneurs and small businesses new to the programs about the range of opportunities and using social media to further engage small business. Fully one-third of our applicants and awardees are new to NIH each year and new to the program, and we believe we are reaching more future applicants and have more effective outreach strategies due to the provisions in the reauthorization.

In February, NIH published a new funding opportunity announcement implementing the SBIR direct Phase II pilot allowing for the first time companies that have established scientific feasibility with non-SBIR and STTR support to bypass the need to apply for Phase I and compete for Phase II directly. We have received the first round of applications in April 2014, and expect to make first funding decisions in early Fiscal Year 2015, and we will be monitoring the impact of this pilot closely on our overall success rates. We are now also able to accept applications that switch programs from SBIR and vice versa at the Phase II or Phase IIB level, which our second sequential Phase II.

In 2013, NIH exercised the authority to allow small businesses that are majority-owned by multiple venture capital companies to apply for SBIR funding. We received the first applications in late Fiscal Year 2013 and have made the first award this fiscal year. The NIH will soon be reducing the time it takes to award funding to our small businesses as required, an objective to which we are strongly committed.

NIH is grateful for the support provided through the administrative fund pilot authority to enhance the management of the SBIR programs in new and more efficient ways. These funds, while currently temporary, have been critical so far in a number of areas across NIH to allow us to increase outreach, hire new staff to help with outreach reporting, and improve our IT infrastructure for more efficient evaluation and management of our award portfolio. This includes our soon-to-be launched redesigned SBIR website, adding functionality to our performance outcome systems to now store commercialization data that will be linked to the new SBA commercialization database and creating other resources for our program managers and the small business community, all of which would not have been possible without the additional funds under this pilot.

We are eager to see the effects of these many changes in the coming years, and I would like to stress that NIH attributes the success and effectiveness of its programs to several factors, the most significant of which is a flexible and proactive approach that adapts to the changing nature of biomedical research.

In conclusion, NIH SBIR projects are stories of discovery. We are committed to doing everything we can to ensure that the small businesses we fund today may become the Marteks, MedImmunes, and Abbotts of tomorrow. These companies, now household names, all received SBIR funding in the early stages and went on to create thousands of new jobs and deliver products that are making a real and significant impact on the lives and health of millions of people.

Thank you for your attention.

Mr. LUETKEMEYER. Thank you, Dr. Portnoy.

We have votes here in probably the next 20 to 30 minutes or so, so I am going to defer my questions, and we will go immediately to Mr. Collins for his five minutes.

Mr. COLLINS. Thank you, Mr. Chairman.

Dr. Portnoy, I am kind of curious where you say or at least allude to someone, a small business could apply for a SBIR grant outside of a solicitation from you and in accordance with your mission. So help me understand. A small biotech company has some idea somewhere that they think is novel, they want to get a grant, you do not have a solicitation. How would they go about that, and is that something, in fact, the NIH is looking for?

Mr. PORTNOY. Thank you for the question, Representative Collins. In fact, everyone who applies to NIH, be it SBIR or any of our mechanisms, do apply to a solicitation. What I meant was that our standard omnibus SBIR solicitation is investigator-initiated, meaning they do not necessarily have to respond to one of the many topics we put out that we are interested in. If a small business has a technology that is in the healthcare or public health space, they can apply to our omnibus solicitation despite the fact that it is not in response to a specific topic. It will receive an external peer review and be considered for funding along with all of our other applications.

Mr. COLLINS. So how does the NIH decide, okay, this is the topic I am looking for in this solicitation? Take for instance the case where we just found that the CDC had live versions of—I am not sure, it was the N5H1 and some other things where they thought they had been neutralized and they had not. Is that something that would catch the attention of the NIH and say, you know, clearly there must be ways of ensuring public safety outside of what transpired recently at the CDC labs?

Mr. PORTNOY. So all of our program managers, each and every year, go through a process to determine what topics are of interest to their institute and within the mission of their institute, and we collect those topics of interest and they receive them from a variety of sources, be it workshops, from their own staff, also from looking through the literature and the technology space to determine what might be missing. And they put those topics together for us. That is not necessarily all inclusive of what may be out there, but that is the process by which we go through developing topics.

Mr. COLLINS. And how easy is it for a small biotech company to find out that your solicitations are out there? Do they have to be looking into your website? Do you send things out? How do you advertise these and make these known throughout?

Mr. PORTNOY. We do many different things, including all of the above. So we do post all of our solicitations on the NIH website, sbir.NIH.gov. We post them through the central NIH portal for all SBIR solicitations, the NIH Guide for Grants and Contracts. We post all of our SBIR solicitations—they are cross-posted on SBIR.gov, which is the central government SBA solicitation repository. In addition, we put out a variety of marketing through our 16,000 plus member list serve, our website, our Twitter feed, and all of our program managers take all of that and remarket through all of their channels.

Mr. COLLINS. Is this mostly Phase I solicitations?

Mr. PORTNOY. Most of our solicitations are, in fact, a combination, and they accept Phase I, Phase II, and what we call Fast Track, which is a combination of Phase I and II award designed to reduce the funding gap between I and II. Some of our solicitations are Phase I only, some are Phase II only, but most accept Phase I and Phase II.

Mr. COLLINS. Now, if it is a Phase II only, would the company have had to already do a Phase I?

Mr. PORTNOY. That is right. That is a little bit separate from the new directed Phase II, which I can address in a moment, but our solicitations, when they accept regular Phase IIs, the company can have received the Phase I from either NIH or any other federal agency and applied to one of our Phase II solicitations if they are proposing work that is within the mission of NIH. Separately, we have a new direct Phase II pilot where the companies must have established the Phase I equivalent feasibility on their own without SBIR support, and then they can apply for the direct Phase II.

Mr. COLLINS. Okay. Good.

Thank you very much, Mr. Chairman. I yield back.

Mr. LUETKEMEYER. Thank you.

With that, we will go to the ranking member, Ms. Velázquez, for five minutes.

Ms. VELAZQUEZ. I will defer to my members.

Mr. LUETKEMEYER. Okay. Mr. Barber for five minutes, from Arizona.

Mr. BARBER. Thank you, Mr. Chairman, and thank you, Ranking Member Velázquez for yielding.

Thank you all for coming. I come from Southern Arizona, border district with Mexico, and it is an area where small businesses, particularly in the high tech optics solar industry are just beginning to thrive actually, and the importance of SBIR and STTR programs are critical to not only what we have done so far but also to continued growth.

I think it is pretty clear, at least to me from my vantage point, that SBIR and STTR programs are some of the most effective programs we have got in the federal government for spurring innovative ideas of job creation. We have globally competitive businesses that have benefitted from these programs, both startups and new companies that have expanded, developing new commercialization

of groundbreaking technologies. For example, the University of Arizona is partnering with small businesses to develop and commercialize new technologies as a part of the small University of Arizona, Southern Arizona SBIR/STTR Competitiveness Initiative. And a good example of that is Avery Therapeutics, which is developing a new therapy to treat heart failure. The University of Arizona is helping the company with an NIH Phase I STTR proposal, as well as helping design appropriate proof of concept experiments to test the safety and efficacy of the therapy and build a small business leadership team and develop long-term commercialization plans. This is essentially a part of what the programs that you represent or have spoken about can do for a community.

So let me turn to you, Mr. Saade. Did I pronounce that correctly?

Mr. SAADE. Close enough.

Mr. BARBER. Okay. For a question about what you are responsible for. Thank you, of course, for being here. And in your testimony, you touched on the commercialization component of these programs. While a small part of SBIR and STTR commercialization makes the most of these investments for the federal government and our small businesses, could you talk about how successful these efforts have been using the current allowed set-asides and how we can better improve or maximize commercialization for small businesses moving forward, particularly with regard to the set-asides?

Mr. SAADE. So, as you know very well, the commercialization aspect of the program is actually one of the main tenets of the program. And the reason why it sits in the agency and within your purview is because this is not only about advancing the frontiers of human knowledge, which is great; it is about creating companies around those. So different agencies do different things to get their products and their research commercialized. And the reason they do different things, obviously, is because the path to commercialization is different, and you have two examples here where in the case of Defense, at the end of the commercialization road it is basically defense. It is a single customer at the end of that road, that that technology creates other uses, and so on and so forth is a different story. NIH, for example, clearly not a sole customer at the end of the road. It is not a contract that the SBIR recipient gets to commercialize.

So there are things that could be better done, and one of the best examples as to what SBA, at least from having a preview of the program, is finding best practices. And one of the things we are looking at is something NSF does to commercialize, to get the scientists that participate in the programs to have a commercial mindset from day one. And the reason is that for the most part, most Ph.Ds. are extremely, extremely good at research, but sometimes they do not think about the business side. So NSF implemented with great success something called I-Corps, Innovation Corps, and it is one of the ways in which we can cross agencies and we are looking at how to do that, begin to export some of these best practices, one of which is I-Corps, one of which enables scientists to begin their research always with a commercial purpose in mind. And NSF has been greatly successful, and right now NIH actually is looking at figuring out how to implement I-Corps in their areas.

Mr. BARBER. Well, Mr. Chairman, I am almost out of time so I will yield back. Thank you.

Mr. LUETKEMEYER. Thank you.

With that, we go to the gentleman from Colorado, Mr. Coffman, for five minutes.

Mr. COFFMAN. Thank you, Mr. Chairman.

Ms. Mak, are there ways to enhance existing data systems, such as the company commercialization reports or federal procurement data systems to enable more comprehensive tracking and reporting of technology transition in the Department of Defense Small Business Innovation Research Program?

Ms. MAK. Thank you, sir, for the question.

The existing systems can only take you so far, and like I said earlier, we believe that the systems were not intended or designed for tracking outcomes and not for tracking for the detailed information about acquisition programs. But I tend to believe there are good practices that DOD could consider that would make incremental improvements to the systems, such as increased training of those responsible for entering data on what is supposed to be reported. However, really it is a partnership that is needed to improve technology transition and commercialization within DoD. We really see it as a partnership between SBIR offices and acquisition offices. It is a push-pull collaboration where SBIR does the technology pushing and the acquisition side does the pulling. There are more ways that DOD can build SBIR considerations into the process for acquiring weapon systems, such as including it in the program acquisition strategy, the planning, and the milestone reviews. In the different phases of the acquisition process, there could be more implementation of SBIR considerations into the process.

Mr. COFFMAN. Thank you.

Mr. Gudger, what level or rate of technology transition success should be expected from the Department of Defense Small Business Innovation Research Program?

Mr. GUDGER. Well, that is a great question. The Department of Defense is big and massive, and that answer will probably vary depending on the military component or defense agency. On average, we see 25 percent of the investments the Department of Defense make go to commercialization, whether it is industry or DoD. So I think it is a very healthy number. And I anticipate that still being the track and trend that we are on.

Mr. COFFMAN. Good.

Dr. Portnoy, about how many in the National Institute of Health, the Small Business Innovation awards utilize the waiver for surpassing the statutorily defined award sizes? And do you have evidence and/or studies that show that larger SBIR awards result in more innovation and better commercialization?

Mr. PORTNOY. Thank you for the question, Representative Coffman.

In terms of the percentage of awards that we make over the statutory hard caps, historically, before the reauthorization, we were at around 20 to 27 percent portion of our awards were over the hard cap and in light of the new reauthorization and the waivers, we do not anticipate that to change very much.

In terms of your second question about—excuse me, can you repeat the question?

Mr. COFFMAN. Do have evidence and/or studies that show that larger SBIR awards result in more innovation and better commercialization?

Mr. PORTNOY. Yes. Thank you.

So we have the 2008 or 2009 Academy study that bolstered the size of our awards. In addition, we are asking the Academies again in the current study to look at that. And we have our own data in terms of how the size of awards is important for making sure that technology gets supported with SBIR to the point where it is being able to be picked up by the next investor. Biomedical research is very expensive, and SBIR typically only is involved in the first 5 to 10 percent of the overall investment before technology gets to the market, and so we strive to fund research at an appropriate level so that a venture capital company, angel investor, strategic partner, pharmaceutical, may pick it up at the appropriate point.

Mr. COFFMAN. Thank you, Mr. Chairman. I yield back.

Mr. LUETKEMEYER. Thank you.

Now we will go to the gentleman from Oregon, Mr. Schrader.

Mr. SCHRADER. Thank you, Mr. Chairman. Appreciate it.

I guess, Mr. Saade, what are the outcome measures that the agency is using for SBIR and STTR with the different players that we have got here?

Mr. SAADE. So one of the things that we looked at, which was actually embedded in the law, is the rate—and this has been brought up a couple of times—is the rate at which Phase Is becomes Phase IIs and at which Phase IIs become Phase IIIs, which is really commercialization. So what is in there is 25 percent. So the goal is for across the program for one out of four SBIR Phase I awards to get Phase II awards. It basically goes to the premise of the program that you are taking probably a little more risk in the very, very early stages of the Phase I and you are hoping that at least one in four make it to Phase II. On the Phase II to Phase III, there are two ways to kind of measure it. One is how much outside investment is—and by outside investment I mean not the taxpayer footing the bill, but an investment firm. It could be a company. It could be a big or small business. And the target there is that for every seven awards—and I have to check on these numbers, but it is something about this, and I will get back to you with the exact numbers, but it is something like every seven awards attracting either—sorry, for every seven awards, one patent, because if the patent is available, the likelihood that the technology will get to market is more likely because there is intellectual property. And the other one has to do with how much outside investment. And I actually do not recall exactly, but it is like 100,000 for every Phase II award, but I will have to check on that.

Mr. SCHRADER. So basically three major outcomes that you are looking for with the SBIR/STTR program?

Mr. SAADE. There are a few milestones, like the ones I mentioned, but we also, because we have a purview obviously of the program across the agencies, there are definitely some best practices. And one of the best practices I mentioned before, which is sort of on the front end of Phase I, basically, you are making sci-

entists go through essentially what is an MBA 101. And the reason for that is that the theory goes or in practical terms, if the researcher and investigator is thinking about what the market segments are going to be for their technology, how they are going to fund it, who are they going to sell it to, MBA 101 type stuff, then the likelihood of that becoming a commercial success is higher. It is logic. So because NSF has been very successful at this, even there are no hard numbers yet, but it costs nothing because essentially you are making the scientists go through this as part of the program, why not blow it out across? So there are some nuggets of interesting best practices that could be used. Yeah.

Mr. SCHRADER. Okay.

Director Mak, you talked about not a lot of outcomes, or at least—insufficient might be a harsh word—outcomes in some of the DoD programs, and yet Director Gudger talked about certain outcomes that sounded reasonable, sounded decent. Could you juxtapose the two conversations for us?

Ms. MAK. I definitely agree. There are success stories. There are numerous outcomes. But it is a matter of tracking, getting comprehensive data to really know to what extent, how many successes are you really having versus just what you can get from the existing systems. There are models within the department that we have found in our work that are very effective in tracking transition outcomes. Like I mentioned earlier, a key example is the Future Naval Capabilities Program. They have a Transition Review Board that regularly reviews their investments, tracks the outcomes, and uses that information to make future investment decisions. Also, SBIR specific, the Program Executive Office for Submarines has been noted for years for actively supporting the SBIR technologies, tracking the outcomes, including it in their program planning milestone reviews, and offering incentives in contracts.

Mr. SCHRADER. I have got limited time. I apologize. So in other words, you are talking about filling in the blanks. In other words, all the programs are considered?

Ms. MAK. Comprehensive data for all the SBIR programs is critical to establishing a baseline.

Mr. SCHRADER. Director Gudger has given a good example of the Department overall, but not to show the micro, into each of the different program areas——

Ms. MAK. Absolutely.

Mr. SCHRADER.—that will help us.

The request I would make as my time expires, it would be interesting—for me, I am just a businessman—but like over the last 10 years, what the trend line has been in the SBIR, maybe STTR programs for the different agencies that get the money or that are supposed to be doing the granting to the different companies. See what the trend line has been, just and the different outcomes areas that the administrator talked about. That would really help me get a picture of how we are doing. It might take into account the fact that we have had a recession. I get that. Or money that has been allocated or not allocated to make the program hopefully as successful as it could be. But if I could get trend lines from the different agencies, that would be really helpful. If I could ask that, Mr. Chairman, going forward.

Mr. LUETKEMEYER. Very good.

Mr. SCHRADER. Thank you.

Mr. LUETKEMEYER. With that, the gentleman from Colorado, Mr. Tipton. Five minutes.

Mr. TIPTON. Thank you, Mr. Chairman. Thank you, panel, for taking the time to be here.

Mr. Gudger, this is a follow up perhaps a little bit on Mr. Schrader's question. You may be able to give us some insight in regards to some of the trending. In the 2012 Reauthorization Bill, the Department of Defense was authorized to be able to establish goals to be able to increase the SBIR's technology transition and to be able to use some incentives, I believe, to encourage prime contractors to be able to meet the goal. Has the DoD implemented these policies, and could you maybe enlighten us a little bit on some of the incentives that were used as well?

Mr. GUDGER. Absolutely. I have been waiting for this question all day.

Mr. TIPTON. That is what I was here for.

Mr. GUDGER. In Fiscal Year 2011, I presented a plan to the House Armed Services in collaboration with the House Small Business Committee, and I laid out this plan about increasing small business participation DoD with a particular focus on technology firms, which meant SBIR/STTR. I wanted to increase commercialization. And in that plan, what we did was look at the acquisition framework. Now, make no mistake about it. The SBIR/STTR programs are within the acquisition community, and so they work hand-in-hand, close already. And in that plan, there were eight actionable items. One of them is a monthly meeting between myself hosted by the Undersecretary for Acquisition Technology and Logistics, and the service acquisition executives in which these technology programs report up to. So that became a best practice. We do that DoD wide. And that led to the standup of our SBIR PEO, which is led by Chris Rinaldi, who is here in the room. That PEO has a specific focus on commercialization, and it works with the Pre-Defense Acquisition Board. All my small business directors now sit on abstracts and peer reviews or anything above 500 million, and we look at how we get small business participation across the board into these major defense programs ACAT One and above. And that led to a great outcome.

And going to Congressman Schrader's point, I have the 2003 data all the way through 2013, and I look at the commercialization number. DoD had 3.5 billion aggregate over time, and just to show you the focus and the results, it goes down to dollars, and we have commercialized 13.5 billion aggregate over a 10-year period. That is significant for small business. And we track that data. And we have a system. We work with SBA. When they come and look at our system, they like it. It is a great model. I am very familiar with all the military departments and how they bring their data together. And they do that in a decentralized way. They make the systems that meet the need for the department, and we bring it in together and we provide that report annually.

And so, I think that we have done the right thing. We have a commercialization working group that the members are the S&T executives from the defense agencies and research and engineering

at the OSD level, and it includes all the directors of small business. So this collaboration happens. We are using technology better, and we are looking to put hooks into the publicly available databases, like FPDS and ESRS that was referred to earlier. Yes, they were not designed originally to collect this kind of information, but there is a however part.

In Fiscal Year 2013, in the NDAA and the authorization, the language I actually supported and pushed for, was for us to work with SBA, GSA, and the members of DoD, and we did that. A tiger team stood up with members from my office, our Procurement Acquisition Policy Office, the contracting folks, GSA, and SBA, and that team looked at the systems and made recommendations on how to improve them. And we want to roll out those recommendations. At the time, we were in the middle of a continuing resolution, so there was limited new starts that we could do, and that would be considered one. But that is an area focused in 2014 and 2015 to make improvements to the technology systems and take the best practices we have in our system that we collect, that data that I can refer to. I have it, and I want to make it available to those public systems where right now we provide that to the SBA.

Mr. TIPTON. Okay, well, thank you.

Mr. Saade, how many agencies have utilized the authority given to them under Section 5123, Reauthorization, and requested to establish a commercialization readiness pilot program?

Mr. SAADE. Eleven agencies participated in the SBIR program, and that is driven by how much of the research budget is—extramural budget is X. And five agencies participate in the STTR program, so 11 and five. It is two different numbers for both programs.

Mr. TIPTON. Okay. Thank you.

Mr. Chairman, my time has expired, and I yield back.

Mr. LUETKEMEYER. Thank you.

With that, I will go to the ranking Member, Ms. Velázquez, for five minutes.

Ms. VELAZQUEZ. Thank you, Mr. Chairman.

Director Gudger, I would like to know if your agency has conducted any training in terms of your DoD SBIR personnel regarding the new procedures put in place by the reauthorization statute.

Mr. GUDGER. Yes.

Ms. VELAZQUEZ. So I guess that your staff briefed you regarding the first oversight hearing that we held on this committee since you were coming to testify regarding SBIR and STTR. Were you?

Mr. GUDGER. I was definitely briefed.

Ms. VELAZQUEZ. Okay. So you heard that a company stated the fact that DoD personnel complained about having to execute a "small business welfare program" and that they denied submission of Phase II proposals from Phase I awardees when they do not have the authority to do so. What do you have to say about that?

Mr. GUDGER. Well, I am not aware of that, and if I was made aware of that, I have an open door policy. I will give my email address. Send me an email and tell me who said that and why they said that, and I will pay a personal visit to them. Because we are focused on capability and technology superiority in the Department of Defense. That is our future, protecting the young men and women. So that means that we have to have Phase II and Phase

II programs in the Department of Defense in order to be successful. So I am not aware of anyone saying they have not done it or they are not going to do it.

Ms. VELAZQUEZ. Well, I just want to make sure that you were briefed regarding those complaints that were shared with us during our committee hearing.

Mr. GUDGER. Yes.

Ms. VELAZQUEZ. The reauthorization legislation made permanent the DoD commercialization program and created a similar pilot program to civilian agencies. This program diverted funds from Phase I and Phase II awards and reallocated them to commercialization efforts. Given that GAO has found DoD lacks the data of commercialization, how are you measuring success?

Mr. GUDGER. Well, I do not concur with GAO's report. I think it is vastly inaccurate. However, we measure success of SBIR by the percentage of commercialization. SBA set those rules and defined them and we adhere.

Ms. VELAZQUEZ. Ms. Mak, would you please comment on Mr. Gudger's characterization?

Ms. MAK. Yes, thank you.

They do track some outcomes, but it is one of those issues where it is not extensive enough. The existing systems, the company commercialization reports and the federal procurement data systems that they use to get the numbers, there are reliability issues when it comes to tracking outcomes, and we found that in our work. We also found what you mentioned earlier, that there is not a complete awareness of the SBIR program throughout all the acquisition communities that are impacted, and therefore, there could be more improvements in those particular areas. And when we talk about databases, we are talking about measuring the extent of success. I don't disagree, there are successes. But until we know what the baseline is, how are they going to report how effective those programs are overall? Until you have comprehensive data that sets a baseline, it is really kind of difficult to determine.

Ms. VELAZQUEZ. Ms. Mak, according to data on SBIR.gov, from 1996 to 2013, women-owned firms' share of SBIR awards by value decreased from 9.8 percent to 6.4 percent, a decline of 35 percent. In the same period, award shares for minority-owned firms fell from 8.3 percent into 2.6 percent, a decline of 70 percent. This happened at a time when women-owned firms grew by 59 percent, about one and a half times the national average, and according to one study, women-owned firms are exceeding overall sector growth in eight of the 13 most popular industries. It looks like in the area of research and innovation, that does not hold water. Why is there that discrepancy?

Ms. MAK. I really cannot comment on that because we did not do work focused on that area, but I do feel that Congress has provided a lot of good provisions, established clear policies of maximizing small business contracting opportunities for women and minorities, but I cannot say much more than that regarding this area.

Ms. VELAZQUEZ. Okay. Ms. Mak, according to data from—well, I believe that this will be the same answer to my question. I would like to ask to Mr. Saade, in May of last year, SBA published guidance on benchmarks for Phase I to Phase II transitions. The goal

of these benchmarks is to prevent the same company from continually winning Phase I awards without progressing to Phase II. Are agencies enforcing these benchmarks? And if so, have there been any cases where the company was made ineligible for the year?

Mr. SAADE. So, yeah, I alluded to this a little bit earlier. The progress to Phase II from Phase I and the progress to Phase III from Phase II respectively, there is a minimum benchmark of 25 percent, so one in four, Phase I to Phase II. And in terms of Phase II to Phase III, if a company has gotten a Phase II in the last 10 years, they must have one of two things. Either an investment or sales of at least $100,000, which indicates commercial success, or a one in seven conversion into intellectual property and IP.

One of the things that I think is going to help us and the Committee look at the success of this is to have one place which basically houses the commercialization data across the SBIR program, and that is something that we are hoping to have live very soon. And it will be basically a repository of data which is going to give us that baseline that Acting Director Mak was talking about. Also, enables ease and efficiency of use for the sectors to commercialize that data.

Ms. VELÁZQUEZ. Okay. So my question is, is SBA tracking and compiling data on firms that are now meeting these benchmarks. Are you doing that?

Mr. SAADE. We are compiling data.

Ms. VELAZQUEZ. Okay.

Mr. Portnoy, you state in your testimony that the current demand for NIH awards from venture-backed companies is low. Why do you believe that this is the case?

Mr. PORTNOY. So as I said in my written testimony, at the moment there is not a high demand for the venture capital-backed provision in our solicitation. It is in all of our SBIR solicitations since the middle of 2013 when we implemented. I do not think there is any one reason, and I just think a variety of reasons in no particular order might be that the provision is new. It takes time for companies—we are doing extensive outreach on that provision, but it takes time for companies to decide to go after SBIR when they have not and to build up the resources and the capability to put in applications. It is also possible that with the new direct Phase II provision, this might be more attractive for venture capital-backed companies to apply as opposed to the Phase I route. But at the moment it is too early to know. We are tracking it, and we will see what happens over time.

Ms. VELAZQUEZ. Under the reauthorization, VC-backed companies must register with the SBA and also note their funding structure in the SBIR program application. Do you think that these requirements serve as a deterrent for VC participation?

Mr. PORTNOY. I do not believe so. They are required in the SBA company registry to put the rough ownership structure of the company, what percentage they have owned by multiple venture capital companies, et cetera, and that is used solely for determining eligibility, whether they fall into the VC eligibility criteria or not. It is not used in any way other than that to determine eligibility.

Ms. VELAZQUEZ. Thank you, Mr. Chairman.

Mr. LUETKEMEYER. Thank you.

I have got just a few questions and then it looks like we are getting ready to call votes here in a minute. And I think Mr. Payne will be able to ask a few whenever he gets settled here as well.

Mr. Saade, we have already kind of asked this question but I want to take a little bit different tact on it. A Cross agencies, what is being done to improve data collection and dissemination, so it is important with reauthorization, it is required, a lot more reporting to you at the SBA and to us here in Congress. It is crucial for us to engage in future reauthorization activities. And so I guess the question really is what are you doing to improve the data collection? I know you have talked about it, but what are you doing to improve the cross agencies?

Mr. SAADE. Thank you for the question.

One of the things in which we play a big role is to ensure that as much of the mandates and the statute as dictated by the reauthorization are done consistently across the agency. So one of the things that was born out of that was five groups which are composed of different and varied program managers from different agencies, one which is solely focused on commercialization and outreach, another one which is focused on asset mapping. Asset mapping meaning the federal government owns billions of dollars of buildings and equipment that are available for use for small businesses. We are trying to figure out where they are so that small businesses can use them. And several other groups.

So one of the roles that we are playing, and the agencies and the program managers are participating in a great way, is to have this cross pollination and cross collaboration between agencies across five very specific groups which are intended to corral what the intent of the reauthorization was, one of which is the standardization of data collection. And there are two things to that I just want to add. One is the data collection of the inbound, which is what allows us to see how many women or minorities are applying because one of the reasons why potentially women and minority awards are down is because they are applying less. That is a different problem than them not getting them. So that is on one end of the spectrum. On the other end of the spectrum is if we make the data surrounding the technologies funded by the taxpayer easy to search, you would think that more private investment dollars are attracted. So that is kind of data from both ends.

Mr. LUETKEMEYER. Very good. Thank you.

Mr. Gudger, what progress has been made in implementing the transition reporting requirements required by the law? Has the plan been developed as GAO recommended to address requirements? If so, how and when will improvements be made in the tracking and reporting of technology transition outcomes?

Mr. GUDGER. Thank you. That was a great question.

We are already tracking them and reporting them. The genesis of what GAO found wasn't necessarily us collecting the comprehensive data as much as it was the validation of that data. And some of the challenges we have in validation of the data is most of the companies that are moving into transitioning programs of record are typically subcontractors. And we have been bound by the self-reporting allowances of the law, not DoD policy, but inside of the comprehensive subcontracting test program, it allows for large com-

panies to self-report and it is very difficult to validate that data. And we had a ripe opportunity here to let that program expire and have transparent reporting into the system that we can validate. That is behind us a little bit, but yes, what we have done in DoD to further implement what we were doing is we updated our DoD 5000, which is our acquisition framework documentation. It is full of transition reporting incentives. We have updated our Defense Acquisition Guidance, which goes to our field, our program managers, and our contracting officers. In addition to that, the Secretary of Defense for the first time in history in 2012 included a small business innovation research and technology transfer, STTR, into the framework of the defense planning guidance, and that was directly to the chairman of Joint Chiefs and Joint Staff, secretary of the military departments, and director of defense agencies to report on transitioning SBIR technologies into their programs. And our defense contract management organization office tracks that. And our office gets an annual report on that and 100 percent of them are compliant in Fiscal Year 2014.

Mr. LUETKEMEYER. One hundred percent. Wow.

Mr. GUDGER. Yeah.

Mr. LUETKEMEYER. Mr. Portnoy, you have kind of answered a little bit about this, but also these two gentlemen, we asked them with regards to the reporting requirements, so we do not leave you out of the questioning here, I know that you are monitoring the extra reporting requirements of SBIR applicants as well, especially those that are majority venture backed. What is the National Institute of Health doing to help ensure that these requirements are not overly burdensome and prohibitive to majority venture backed small companies?

Mr. PORTNOY. Well, I think Mr. Saade emphasized it quite well in that SBA is developing central data systems so that the burden is less on all of our awardees, including venture backed. So SBA is about to launch a commercialization database. They already have an award database and a registry, and so we will be requiring through the policy directive of SBA all of our awardees to report their outcomes in the central SBA database.

Mr. LUETKEMEYER. Not to interrupt, but just a question to follow up. Do you ever get feedback from the applicants themselves about whether the application process is burdensome or not, whether the amount of information, the constant rules and regulations, do they ever give you any feedback and say this is just right or this is not enough or this is way too much?

Mr. PORTNOY. Well, I do not believe they ever tell us that it is too little, but we do get feedback, and we have to, of course, follow all of the rules within the policy directive and the law, and follow all of our own regulations in terms of collecting what we need in an application to assure a fair and unbiased view.

Mr. LUETKEMEYER. We cleared that half of the spectrum. What about the other half of the spectrum? Do you get complaints from the applicants about how burdensome it is? How much it costs to comply? How much time it takes?

Mr. PORTNOY. We do not get complaints about time or cost. There are a lot of forms to apply for any type of federal funding,

and that is to ensure that the funds are spent and used appropriately.

Mr. LUETKEMEYER. Very good. Thank you.

With that, Mr. Payne, if you are ready, you have got five minutes.

Mr. PAYNE. Mr. Chair, let us see. I was ready.

I had a question for Mr. Gudger. I understand the Department of Defense uses multiple outreach methods to increase the participation of women and minority-owned businesses. Do you find that this outreach has been effective?

Mr. GUDGER. Yes. What we see, we actually have very healthy numbers in the women and minority areas for SBIR and STTR. When we look at minority-owned participation in SBIR, it is 6 percent. The federal goal is 5 percent.

Mr. PAYNE. Six, you said?

Mr. GUDGER. Yes, six. It is greater than the goal. And in women, it is 14 percent, which also is greater than the 5 percent goal. So we have a healthy mix of women and minorities now participating in SBIR and STTR.

Mr. PAYNE. Maybe the goal should be raised.

Mr. GUDGER. Well, talk to SBA on that one.

Mr. PAYNE. So, but earlier you mentioned, you said that the numbers were down—the associate administrator, did you mention that the minority outreach goals were down? No? Oh, good.

Also, in 2011, reauthorization allows for up to 3 percent of small business innovation research funds to be used for program management and administration purposes, including outreach. Is the Department of Defense using the full 3 percent available? And what has this additional funding allowed the DoD to do that if it had not been available otherwise?

Mr. GUDGER. So, yes. We do use a portion of the 3 percent in administering the SBIR program. It is a billion dollar program for us, so we use a small percentage of that to do the administration. It is very complex. I have a posture that we need to be slim and trim and be innovative with our outreach. We need to use technology where available. And we should use those additional administrative funds where appropriate to help small business commercialize their technologies. So for us, we use a significant portion, maybe a percent and a half in the administration, which is very helpful. Thank you for that. And the other half goes into—directly back to small businesses, which is where it belongs.

Mr. PAYNE. In the interest of time, Mr. Chair, I will yield back.

Mr. LUETKEMEYER. Thank you.

With that, I would like to thank the witnesses for being with us today.

The SBIR Reauthorization Act was signed into law 31 months ago. That law instructed participating agencies to improve their data collection, focus more on the commercialization of SBIR technologies, and set goals for inclusion of those technologies in larger programs. Agency compliance thus far seems to have been a mixed bag. By and large, SBIR and STTR programs are performing very well, but we can always do better. Agencies need to continue to be partners with us here in Congress to increase participation, commercialization, and provide American taxpayers the greatest return

on their investment. This Committee will continue to follow the progress of the agencies implementing the changes and hope to see better results in the coming months.

I ask unanimous consent that members have five legislative days to submit statements and supporting materials for the record. Without objection, so ordered.

This hearing is now adjourned.

[Whereupon, at 2:13 p.m., the Committee was adjourned.]

APPENDIX

Chairman Graves, Ranking Member Velazquez and distinguished members of the committee, thank you for inviting me here today to discuss the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

I would like to begin with an example. We know about Parkinson's disease, and have observed the way it can impact a person's life. It makes doing simple tasks, like eating, very tough and millions are impacted by it.

A San Francisco-based startup called LiftLabs created an "anti-tremor" spoon that cancels up to 70% of the hand tremors, which allows an individual to eat a bowl of cereal. This startup can thank NIH's SBIR program for the initial seed financing of $800,000 to get their product, LiftWare, developed and deployed into the market. The company, subsequently, raised $1,000,000 in private capital and received the backing of RockHealth, a health-care focused accelerator based in San Francisco's Mission Bay neighborhood—the type of accelerator whose model we are looking to export to the rest of the country through SBA's Growth Accelerator program.

The SBIR and STTR programs do more than just provide grants and contracts. They enable and empower entrepreneurs to pursue innovative ideas that turn into inventions that, in turn, make peoples' lives easier and more fruitful. These programs change the world for the better through next generation science and technology development. These programs touch and affect the research of hundreds of thousands of STEM educated professionals across the country. They also stimulate the demand for people considering academic careers in STEM. This is a critical pillar of our national competitiveness.

SBIR and STTR are programs that pay for themselves many times over. Another example is IDEC Pharmaceuticals, now known as Biogen Idec, which used early SBIR funding to develop breakthroughs in cancer drugs, such as Rituxan, the therapy of choice for Non-Hodgkins Lymphoma patients. Biogen's drugs have saved and improved the lives of millions of people around the world. To me SBIR is personal, my father, Jose, has been in remission for 6 years and literally owes his life to Rituxan.

This one company alone is worth $76 billion dollars today. The wealth created by this one SBIR recipient is double what American taxpayers have invested in these programs over the last three decades.

There are many more examples. We've helped seed innovation-driven companies like Qualcomm and Symantec in their infancy. About 25 percent of *R&D Magazine's* top 100 innovations came from companies that received an SBIR grant. The development of 3D printing and additive manufacturing are attributable to SBIR financing from NSF in 1994. These programs are responsible for truly impressive companies and industries.

The 11 agencies that participate in SBIR and STTR programs have awarded over 145,000 grants totaling about $38 billion dollars to America's small businesses, over the programs history. In 2012, the SBIR and STTR programs provided over $2-1/2 billion dollars directly into the hands of small businesses nationwide. Nearly a quarter of that money was awarded to women-owned, minority-owned, or HUBZone located small businesses.

Thanks to this committee, the SBIR and STTR programs were reauthorized. The reauthorization of the programs enabled several important changes including:

- allowance of majority ownership by multiple investing firms;
- funding for outreach, commercialization, better program management, and prevention of fraud/waste/abuse;
- the introduction of performance benchmarks; and
- significant streamlining of the award process.

The SBA's role, in both the SBIR and STTR programs, is to provide programmatic and policy oversight, SBA works closely with agency program managers and external stakeholders to ensure that the intent of Congress is carried out in the operation of the programs. We have taken the lead to hold regular meetings to ensure timely implementation of the reauthorization provisions and have updated the SBIR and STTR policy directives to guide those changes. While there is one SBIR program, the agencies operate it 11 different ways so as to maximize technology innovation in the areas of the agency's mission directive and goals. The same goes for the five affiliated STTR programs.

The SBA established five working groups to implement the directives in the reauthorization and to support the White House's Lab-to-Market Commercialization agenda. Each of the working groups is co-chaired by a mix of agency program managers and SBA. The five groups are:

(1) the commercialization group,

(2) the databases and interagency exchange of information group,

(3) the award efficiency and efficacy group,

(4) the outreach and communications group, and

(5) the asset mapping group.

To maximize the commercialization and worth of our investments, SBA will be launching a new commercialization database. This will allow the private sector to easily search SBIR and STTR funded research and increase the opportunities to invest in small businesses.

These groups have made the SBIR and STTR programs better for the American entrepreneur and small business owner. They uncover and deploy best practices across the agencies, an example of which is the expansion of NSF's Innovation Corps Teams, known as I-Corps, to NIH.

The General Accountability Office (GAO) conducts annual reviews of these two programs. On the recommendation of GAO, SBA has updated its Policy Directives to clarify spending requirements and has ongoing discussions with agency program managers on the requirement for timely submission and the methodology for extramural budget calculations. We work diligently to raise awareness about these important programs. We have spoken at conferences, partnered with our colleagues in SBA's Office of Entrepreneurial Development and are working with the National Council of Entrepreneurial Tech Transfer and the Small Business Technology Council. In June, SBA and the 11 agencies hosted the annual SBIR and STTR National Conference at the National Harbor. It was a widely attended event and an overwhelming success, with participants who joined in workshops, panels, and exhibitions that showcased the energy of our dynamic small innovative technology companies.

Delegations from around the world (Finland, Japan, Italy, Ukraine, Germany, Great Britain, India, etc.) visit our office regularly to learn about these world-class innovation programs. These programs make up the largest seed investing pool on the globe. While we are still the undisputed world leader in innovation, we are not alone and many countries are making serious commitments to their own innovation efforts. Today, China is investing billions of dollars and thousands of engineers in its space program. We need to continue to invest in our future as others catch up so that we may be able to maintain our leadership for the 21st Century.

To maximize the commercialization and worth of our investments, SBA will be launching a new commercialization database. This will allow the private sector to easily search SBIR and STTR funded research and increase the opportunities to invest in small businesses.

Allow me to close with another success story. iRobot is another amazing success story, creator of the Roomba vacuum cleaner which has become a household name. This company earned over $10M in SBIR funding from DOD. iRobot pivoted its military designed technologies towards mainstream consumer needs. This is a truly remarkable example of an entrepreneur spotting a dual-use of a technology originally developed for DOD.

In FY 2013, iRobot generated over $487M in revenue and employed over 500 people. This is a truly inspiring example of an entrepreneur enabling multiple uses of a technology developed for DOD.

The SBIR and STTR program are foundational components of America's economic growth and are keys to progressing to the next generation of science and technology development. Job creation is a national goal. Job creation plus innovative research leads to international competitiveness.

As Associate Administrator for SBA's Office of Investment and Innovation, I will continue to work closely with our agencies to ensure the SBIR and STTR programs are highly prioritized, I will hold agencies responsible for the allocations required by statute, and I will continue to work with you to improve these programs.

They are true gems, and we will make sure our small businesses know about these opportunities.

United States Government Accountability Office

GAO

Testimony
Before the House Committee on
Small Business

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SMALL BUSINESS INNOVATION RESEARCH

DOD's Program Has Developed Some Technologies that Support Military Users, but Lacks Comprehensive Data on Transition Outcomes

Statement of Marie A. Mak, Acting Director,
Acquisition and Sourcing Management

GAO-14-748T

July 23, 2014

GAO Highlights

Highlights of GAO-14-748T, a testimony before the House Committee on Small Business

SMALL BUSINESS INNOVATION RESEARCH

DOD's Program Has Developed Some Technologies that Support Military Users, but Lacks Comprehensive Data on Transition Outcomes

Why GAO Did This Study

DOD relies on its research and development community to identify, pursue, and develop new technologies that improve and enhance military operations and ensure technological superiority over adversaries. The SBIR program is a key mechanism for DOD to use small businesses to meet its research and development needs; stimulate technological innovation; foster and encourage participation by minority and disadvantaged persons in technological innovation; and increase private sector commercialization of innovations derived from federal research and development funding. DOD is the largest SBIR participant in the federal government, with over $1 billion spent annually on the program.

This testimony is based primarily on a report GAO issued in December 2013 and addresses: (1) practices the military departments use to facilitate the transition of SBIR technologies, (2) the extent to which these technologies are successfully transitioning to military users, such as weapon system programs or warfighters in the field, and (3) DOD's efforts to meet fiscal year 2012 NDAA transition reporting requirements. This statement draws from the 2013 report and other work GAO has conducted on technology transition activities in DOD's science and technology programs.

View GAO-14-748T. For more information, contact Marie A Mak at (202) 512-4841 or makm@gao gov

What GAO Found

Transitioning technologies from defense research and technology development programs, such as through the Small Business Innovation Research (SBIR) program, to military users has been a long-standing challenge for the Department of Defense (DOD). Over the past decade, Congress and DOD have taken several steps to address transition challenges in DOD's SBIR program. For example, the military departments can offer additional SBIR funding to certain awardees to supplement or extend technology development projects in order to move them closer to transition. Additionally, each of the military departments has a network of transition facilitators who work directly with small businesses, military research laboratories, and the acquisition community to foster transition opportunities. Further, in fiscal year 2012, Congress provided federal agencies the opportunity to use more of SBIR funding (up to 3 percent) for program administrative purposes, including activities that facilitate transition. However, at times, promising technologies are not taken advantage of because their potential has not been adequately demonstrated, they do not meet military requirements, or users are unable to fund the final stages of development and testing.

GAO found that DOD's SBIR program has developed some technologies that successfully transitioned into acquisition programs or fielded systems, but the extent of transition is unknown because comprehensive and reliable transition data are not collected. The military departments collect information on selected transition "success stories" on a somewhat ad hoc basis from SBIR program officials, acquisition program officials, prime contractors, or directly from small businesses. In addition to these less formal transition tracking efforts, the military departments use, to varying degrees, two data systems—Company Commercialization Reports and the Federal Procurement Data System-Next Generation—to identify transition results program-wide. While these systems provide high-level commercialization information that the departments use to track progress in achieving overall program goals, the systems have significant gaps in coverage and data reliability concerns that limit their transition tracking capabilities. In addition, the systems are not designed to capture detailed information on acquisition programs, fielded systems, or on projects that did not transition.

The National Defense Authorization Act (NDAA) for fiscal year 2012 directed DOD to begin reporting the number and percentage of SBIR projects that transition into acquisition programs or to fielded systems, among other things. DOD acknowledged that it may need to modify its existing data systems or develop new tools to compile more complete and accurate technology transition data. At the end of 2013, DOD was still assessing how to comply with the new transition reporting requirements, and had not established a specific plan, as GAO had recommended, for how and when it would be able to meet the requirements. In a recent update, DOD officials confirmed that alternatives are still being evaluated and no plan for improving the tracking and reporting of technology transition has been completed. Without better information on technology transition outcomes, questions will remain as to whether the DOD SBIR program is providing the right technologies at the right time to users, using effective approaches to select, develop, and transition technologies, and providing tangible benefits.

United States Government Accountability Office

Chairman Graves, Ranking Member Velázquez, and Members of the Committee:

I am pleased to be here today to discuss the Department of Defense's (DOD) Small Business Innovation Research (SBIR) program and its efforts to transition technologies to military users, such as weapon system acquisition programs and the warfighters in the field. DOD relies on its research and development community—government research laboratories, test facilities, industry, and academia—to identify, pursue, and develop new technologies that improve and enhance military operations and ensure technological superiority over adversaries. The SBIR program is a key mechanism for the department to (1) use small businesses to meet its research and development needs; (2) stimulate technological innovation; (3) foster and encourage participation by minority and disadvantaged persons in technological innovation; and (4) increase private sector commercialization of innovations derived from federal research and development funding.[1] DOD is the largest SBIR participant in the federal government, with over $1 billion spent annually on SBIR contract awards, which are implemented across 13 military departments and defense agency components.[2]

The Small Business Administration (SBA) is responsible for establishing the broad policy and guidelines under which individual agencies operate SBIR programs. Within DOD, the Office of Small Business Programs (OSBP) oversees SBIR program activities, develops policy, and manages program reporting. This office generally relies on the components, such as the departments of the Army, Air Force, and Navy, to oversee and execute their own SBIR program activities. Each component has flexibility to tailor its SBIR program to meet its needs, including determining what type of research to pursue, which projects to fund, and how to monitor

[1] Pub. L. No. 97-219.

[2] Every federal agency with a budget of $100 million or more for extramural research and development is required to use a portion of its budget—not less than 2.8 percent in fiscal year 2014—to establish and operate SBIR programs. The 13 DOD SBIR components include the three military departments—Air Force, Army, and Navy—as well as the Missile Defense Agency, Defense Advanced Research Projects Agency, Chemical Biological Defense, Special Operations Command, Defense Threat Reduction Agency, National Geospatial-Intelligence Agency, Defense Logistics Agency, Defense Microelectronics Activity, Defense Health Program, and the Office of Secretary of Defense.

ongoing projects. The SBIR program is structured into three phases, which are described in table 1.

Table 1: DOD Small Business Innovation Research (SBIR) Program Framework

Phases of SBIR	Typical project duration & funding	Sources of funding
Phase I: Agencies competitively select projects based on scientific and technical merit, applicant's past SBIR performance, and potential for commercial application. Focus of work conducted in this phase is on determining project feasibility and merit.	6 months, up to $150,000	SBIR program funding
Phase II: Small businesses with Phase I projects that have demonstrated potential may compete for additional awards to continue further technology development and prototyping. In general, projects should have confirmed interest in transition from a user.	2 years, up to $1 million	SBIR program funding, can include external funding
Phase III: Small businesses pursue commercialization of technology developed in prior phases. Work conducted in this phase derives from, extends, or completes an effort made under prior phases, but it is funded by sources other than the SBIR program. In this phase, businesses are expected to obtain funds from private investors, the capital markets, or government agencies.	Unlimited	Non-SBIR government or private-sector funding

Source: DOD program documentation. | GAO-14-784T

In the context of the SBIR program, commercialization is defined broadly to include the process of developing, producing, and delivering products, processes, technologies, or services for sale to, or use by, the federal government or commercial markets.[3] For DOD, a primary goal of commercialization is the transition of SBIR-developed technologies to weapon system programs or directly to warfighters in the field.

In December 2013, we reported on the practices the military departments use to facilitate the transition of technologies developed through the SBIR program, the extent to which technologies are successfully transitioning to military users, and DOD's efforts to meet transition reporting requirements established by the National Defense Authorization Act (NDAA) for fiscal year 2012.[4] My testimony today focuses primarily on the findings of our

[3] Small Business Administration, Office of Investment and Innovation, *Small Business Innovation Research (SBIR) Program: Policy Directive*, February 24, 2014.

[4] GAO, *Small Business Innovation Research: DOD's Program Supports Weapon Systems, but Lacks Comprehensive Data on Technology Transition Outcomes*. GAO-14-96 (Washington, D.C.: December 20, 2013).

2013 report, but also draws from other work we have conducted on technology transition activities in DOD's science and technology enterprise.[5] More detail on our scope and methodology is included in these issued products. The work on which this testimony is based was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Several Mechanisms Have Been Established Over Time to Help Facilitate SBIR Technology Transition

Transitioning technologies from defense research organizations and technology development programs, such as the SBIR program, to military users has been a long-standing challenge for DOD. To address technology transition challenges in DOD's SBIR program, Congress and DOD have established several program provisions and mechanisms over the past decade, including the following:

- Congress directed the establishment of the Commercialization Pilot Program, subsequently renamed the Commercialization Readiness Program, in fiscal year 2006 to accelerate the transition of SBIR-funded technologies to Phase III, especially those that lead to acquisition programs and high priority military requirements, such as fielded systems. As part of the program, Congress authorized the military departments to use up to 1 percent of SBIR funding to administer the program. This funding is used to provide assistance to SBIR awardees, including efforts to enhance networking and build relationships among small businesses, prime contractors, and DOD science and technology and acquisition communities.[6]

[5] GAO, *Defense Technology Development: Technology Transition Programs Support Military Users, but Opportunities Exist to Improve Measurement of Outcomes.* GAO-13-286 (Washington, D.C.: Mar. 7, 2013); and *Best Practices: Stronger Practices Needed to Improve DOD Technology Transition Processes.* GAO-06-883 (Washington, D.C.: Sep 14, 2006).

[6] National Defense Authorization Act for Fiscal Year 2006, Pub. L. No. 109-163, § 252 as amended by the National Defense Authorization Act for Fiscal Year 2012, Pub. L. No 112-81, § 5122(a) (2011).

- Each military department's SBIR program also has a network of transition facilitators who manage the Commercialization Readiness Program and other SBIR activities that support technology transition. The facilitators are located at military laboratories, acquisition centers, and program executive offices and work directly with government stakeholders to help ensure projects are responsive to warfighter needs. Although the roles and responsibilities vary somewhat across the military departments, in general, transition facilitators foster ties among small businesses, military research laboratories, and the acquisition community in support of transition opportunities, and monitor project progress, including outcomes. Further, the military departments conduct conferences and workshops to provide opportunities for SBIR companies to interact with users and showcase their projects. In the fiscal year 2012 reauthorization of the SBIR program, Congress authorized a pilot effort to allow the DOD SBIR program the opportunity to use more of their SBIR funds (up to 3 percent) for program administration, technical assistance, and commercialization and outreach activities.[7]

- In addition, DOD SBIR components may offer special awards that supplement or extend Phase II projects. The military departments have developed mechanisms to do this, which provide awardees additional SBIR funding to move Phase II projects closer to transition. In some cases, the military departments require formal technology transition agreements or matching funding from intended military users as a condition to receiving the additional Phase II funding. Technology transition agreements, which Air Force and Navy officials reported using, help manage project expectations and formalize stakeholder commitments by outlining cost, schedule, and performance expectations for transition to occur. Matching funds from intended users, which are required by the Navy for some projects, can help create greater buy-in for transition because the intended users have a monetary stake in the project.

- In fiscal year 2011, Congress required the Secretary of Defense to establish a program to accelerate the fielding of technologies developed pursuant to Phase II of the SBIR program, technologies developed by defense laboratories, and other innovative

[7] Pub. L. No. 112-81, § 5141(a) (2011).

technologies.[8] As a result of this new requirement, the Secretary established the Rapid Innovation Program, which received about $430 million in fiscal year 2011 and $175-$225 million annually in subsequent years. According to DOD officials, the majority of projects awarded in the first few years of the program have been to SBIR Phase II awardees. We are currently conducting a review of the program and its transition outcomes for the Senate Armed Services Committee.

Sometimes technologies are not ready to transition when needed because they may still be too risky or costly to adopt. Further, at other times, promising technologies are not taken advantage of because their potential has not been adequately demonstrated or recognized, they do not meet military user requirements, or users are unable to fund the final stages of development and testing. As we have reported in the past on DOD science and technology programs, factors that facilitate successful transition outcomes include selecting the right projects—those that address military needs, have realistic cost and schedule expectations, and have technologies that can be matured or demonstrated—and ensuring early and sustained commitments from intended users and other key stakeholders throughout projects.[9]

[8] Ike Skelton National Defense Authorization Act for Fiscal Year 2011, Pub. L. No. 111-383, § 1073(a).

[9] GAO, *Defense Technology Development: Management Process Can Be Strengthened for New Technology Transition Programs*, GAO-05-480 (Washington, D.C.: June 17, 2005).

DOD's SBIR Program Has Developed Some Technologies that Support Military Users, but Lacks Comprehensive Data on Transition Outcomes

In our 2013 review, we found that the military department SBIR programs have identified some technologies that successfully transitioned into acquisition programs or fielded systems over the past several years, but the extent of transition is unknown because comprehensive and reliable transition data are not collected. The military departments collect information on selected transition "success stories" on a somewhat ad hoc basis from SBIR program officials, acquisition program officials, prime contractors, or directly from small businesses. These success stories cover a broad range of technologies and products. One SBIR transition example from the Air Force was an antenna that transitioned to an unmanned air system that was undergoing operational evaluations in Afghanistan to demonstrate identification and detection capabilities for improvised explosive devices. Another transition success reported by the Army was a sensor system for identifying structural fatigue or damage on Black Hawk helicopters that was undergoing further testing. In addition to less formal transition tracking efforts, the military departments use, to varying degrees, two data systems—Company Commercialization Reports (CCR) and the Federal Procurement Data System-Next Generation (FPDS-NG)—to identify transition results for their programs. While these systems provide high-level commercialization information that the departments use to track progress in achieving overall program goals, the systems have significant gaps in coverage and data reliability concerns that limit their transition tracking capabilities. In addition, the systems are not designed to capture detailed information on acquisition programs, fielded systems, or on projects that did not transition. Table 2 more fully describes these transition data sources and their limitations.

Table 2: DOD Small Business Innovation Research (SBIR) Program Transition Data Sources Overview

Transition data source	Description	Data limitations
Company Commercialization Reports (CCR)	• DOD SBIR database derived from commercialization reports submitted by small businesses as part of applications for new DOD SBIR awards. Companies report on their commercialization history for prior Phase II awards received, including sales resulting from, and investments associated with the awards (non-SBIR funds). DOD-specific commercialization activities are also reported. • Reported commercialization results used by SBIR program management when evaluating future awards to previous SBIR participants (i.e., as a gauge of a firm's ability to commercialize products).	• Do not capture all commercialization data. Only small businesses seeking additional SBIR awards are requested to report Phase III commercialization; data for past SBIR participants that do not pursue new awards is limited. • Self-reported data poses reliability and completeness challenges because of the potential for misreporting. • Collection of data on the specific military user of the technology is inconsistent, at best. Specific users include acquisition programs, such as the F-35 Joint Strike Fighter.
Federal Procurement Data System-Next Generation (FPDS-NG)	• FPDS-NG is the primary government-wide contracting database that provides information on all government contracting actions. • System includes a data field through which contracting officers can identify contracts with SBIR associations. • It can be used to identify Phase III commercialization awards that result in government contracts.	• Does not capture all commercialization data; limited to government contracts. • Not designed to provide commercialization data for subcontracting between a prime contractor and a SBIR recipient; DOD officials indicated this type of commercialization is prevalent. • Contract miscoding of SBIR lineage can cause over- or under-reported commercialization results; DOD officials indicated that contracting officers have challenges in correctly coding contracts, including contracts sometimes being wrongly associated with SBIR as well as contracts failing to be acknowledged as SBIR-related. • Does not directly collect data on the specific military user of the technology. Specific users include acquisition programs, such as the F-35 Joint Strike Fighter.
Agency-specific SBIR transition documentation activities	• To varying degrees, military department programs track status and completion of SBIR projects via internal management systems and input from transition agents, users, and small businesses. • Programs also collect success stories for a select amount of projects and make them available using tools such as annual reports and web-accessible databases.	• Do not capture all commercialization data; SBIR programs tend to track subsets of Phase II projects, such as Commercialization Readiness Program and Phase II Enhancement projects. • Tracing SBIR lineage to technologies is a stated challenge because it is resource-intensive and technologies evolve over time. • Data collection is somewhat ad hoc and internal tracking tool use is varied.

Source: GAO analysis of DOD SBIR systems and program documentation. | GAO-14-784T

DOD is in the Early Stages of Developing a Plan to Improve Technology Transition Reporting

New reporting requirements in the NDAA for fiscal year 2012 directed DOD to begin reporting new SBIR-related transition information to SBA, which is to be included in SBA's annual report to designated congressional committees.[10] This requirement includes reporting on the number and percentage of Phase II SBIR projects that transitioned into acquisition programs or to fielded systems, effectiveness of incentives provided to DOD program managers and prime contractors, and additional information specific to the transition of projects funded through the Commercialization Readiness Program. This type of information is not currently captured by the existing data sources described in table 2.

At the time of our 2013 review, DOD was still assessing how to comply with the new transition reporting requirements directed by Congress, and no specific plan that included a time line for meeting the requirements had been established. DOD acknowledged that it may need to modify its existing data systems or develop new tools to compile more complete and accurate technology transition data, but cited several challenges to obtaining better data. One challenge we found in 2013 was that the military departments and components define technology transition differently—with definitions ranging from any commercialization dollars applied to a project, to only when a technology is actually incorporated into a weapon system or in direct use by the warfighter—and no consensus had been reached on a standard definition to use. We recommended that DOD establish a common definition of technology transition for all SBIR projects as a key step to support annual reporting requirements. Additionally, according to DOD SBIR officials, tracking transition outcomes can be challenging because of the sometimes lengthy period that can occur between SBIR project completion and transition to a DOD user. In some cases, the time lag can be several years and make it difficult to track projects and obscure a project's SBIR linkages. Time lags can occur because of delays in funding availability, additional development or testing needs before transition, or schedule delays encountered by intended users. Officials also stated that limited resources for administrative activities constrain the SBIR program's ability to effectively follow up on the transition outcomes for completed projects. Conversely, military users, such as weapon system acquisition programs, often do not dedicate resources to monitor or track SBIR projects and their likelihood to transition.

[10] Pub. L. No. 112-81, § 5122(a) (2011).

In 2013, DOD officials indicated that addressing the transition reporting requirements would be a long-term effort because of data collection challenges such as those identified in table 2. As a first step, DOD initiated an assessment last year of different options for enhancing transition data, which included examining whether CCR or other existing DOD data sources could be modified to improve reporting, such as Selected Acquisition Reports—annually required for major defense acquisition programs. In addition, opportunities to build more SBIR awareness directly into acquisition program activities were being considered, such as including SBIR-specific provisions in acquisition strategy documents or formal program reviews. Despite these activities, DOD had not established a plan for how and when it would be able to meet the reporting requirements and begin to provide the technology transition information expected by Congress. As such, we recommended in 2013 that DOD develop a plan to meet new technology transition reporting requirements that will improve the completeness, quality, and reliability of SBIR transition data, and report this plan to Congress, including specific steps for improving the technology transition data. In a recent update to our 2013 work, DOD officials confirmed that alternatives are still being evaluated and no plan for how and when it would improve the tracking and reporting of technology transition has been completed.

While we recognize there are challenges to improving transition data, we continue to believe it is important for DOD to develop and implement a plan for obtaining more comprehensible and reliable measures of transition. Without better information on technology transition, questions will remain as to whether the DOD SBIR program is providing the right technologies at the right time to users, using effective approaches to select, develop, and transition technologies, and providing tangible benefits. As we have reported in the past through other work on DOD science and technology activities, tracking technology transitions and the impact of those transitions, such as cost savings or deployment of the technology in a product, provides key feedback that can inform the management of programs. In particular, we found that leading commercial companies tracked technology transition not only to enable them to measure success, but also to assess their processes and determine what changes are necessary to improve transition rates. In addition, we found a few examples of unique efforts within DOD where transition outcomes were being effectively monitored and documented. The Navy, for instance, uses a Transition Review Board to assess whether projects in

its Future Naval Capabilities technology development program are being utilized in systems that support Navy warfighters.[11] For example, the Navy determined that of the 155 technology products the Future Naval Capabilities program delivered to acquisition programs between fiscal years 2006-2011, 21 percent were subsequently deployed to fleet forces, 35 percent were still with the acquisition programs, and 44 percent failed to deploy. For projects that did not successfully deploy, the board assessed whether there were other benefits achieved, such as whether technologies were leveraged for follow-on science and technology work. The board also identifies obstacles to transition, such as loss of interest by the user or inadequacy of funding. These findings are then used to inform the Navy's annual review process and inform future science and technology investment decisions.

Overcoming the challenges to obtaining better technology transition information may ultimately require closer collaboration between the DOD SBIR and acquisition communities. While incremental improvements may be possible by modifying the existing CCR and FPDS-NG data systems and increasing SBIR program managers' capacity to track projects, greater insights into transition outcomes and the benefits the technologies provide to military users may not be achieved without additional information obtained from users, such as acquisition program managers. In an environment of declining budgets, it is important that information on technology transition outcomes for SBIR projects be improved for DOD to identify the extent to which the program is supporting military users and determine whether existing monitoring and transition efforts are working effectively. We recognize that the goal is not to transition all technologies funded through SBIR, because not all technologies will be demonstrated successfully. Nonetheless, it is important to ensure that the right technologies are transitioning and to not allow these technologies to fail for the wrong reasons.

Chairman Graves, Ranking Member Velázquez, and Members of the Committee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

[11] The Future Naval Capabilities program is a key Navy technology development activity, for which nearly $450 million was budgeted in fiscal year 2013 to develop a broad range of technologies. The program, which was initiated in 1999, seeks to provide the best technology solutions to address operational requirements, delivering technology products to acquisition programs that enhance capabilities within a 5-year time frame.

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Testimony of

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House Committee on Small Business

Review of the Department of Defense (DoD) Small Business Innovation Research (SBIR) Program and Small Business Technology Transfer (STTR) Program Implementation of P.L. 112–81

July 23, 2014

Thank you for the opportunity to testify on the Department of Defense Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer (STTR) program. I welcome this opportunity to provide a perspective on how the changes made by Division E of P.L. 112–81, the SBIR/STTR Reauthorization Act of 2011, have been implemented and managed within the Department. The programs are tools for the Department of Defense (DoD) to seed innovation in our industrial base, and, in so doing, develop leading-edge technologies with the potential to meet warfighter needs, today and in the future. Now, more than ever, we need to leverage the responsiveness, efficiency, capability, and technological innovation our nation's small businesses provide.

One of our central obligations as public officials is to ensure that we are using taxpayer dollars as productively and efficiently as possible. From that perspective, today I will provide an overview of the SBIR and STTR programs, steps taken to comply with the most recent authorization of the program, and the overall health of the program.

SBIR and STTR at DoD

The Office of Small Business Programs (OSBP) provides oversight to the DoD SBIR/STTR program which currently has thirteen participating DoD Components comprising of the Military Departments, Defense Agencies, and other Defense Activity programs.

Thirteen DoD Components participate in our SBIR and STTR programs, including the Military Departments and several Defense Agencies. Each Component manages its portion of the overall program to be responsive to specific mission and technology research and development needs while supporting overarching Department science and technology requirements. In terms of budget, the Department's program represents over 50 percent of the total federal SBIR budget, which exceeds two billion dollars.

The SBIR and STTR program fund a significant amount of research and development in any given year. In Fiscal Year 2013, over 9,676 Phase I and approximately 1,500 Phase II proposals were received, which resulted in over 1,500 Phase I and 950 Phase II contract awards. Of those awards, over 450 went to universities.

The SBIR and STTR programs are important for small businesses and the Department. The results of our commercialization efforts indicate that for every dollar invested in a small technology firm through the SBIR and STTR programs, two dollars of Phase III funding are invested in these firms for follow on work. Phase III dollars and commercialization success stories are self-reported through the OSBP Company Commercialization Report (CCR) system database.

DoD Implementation of the SBIR/STTR Reauthorization

On December 31, 2011, the President signed into law the National Defense Reauthorization Act of Fiscal Year 2012, which included the SBIR/STTR Reauthorization Act of 2011, extending the programs through September 30, 2017. The SBIR/STTR Reauthor-

ization Act includes many changes and pilot programs aimed at enhancing the SBIR and STTR programs, targeted to strengthen the role of innovative small business concerns in Federally-funded research and development. Implementation of these changes was planned and executed in the areas of outreach, commercialization, streamlining and simplification, reporting, and compliance.

The Department uses multiple outreach methods to increase the understanding of the SBIR and STTR programs and encourage participation by small technology firms, particularly underserved firms such as women-owned small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, small disadvantaged businesses, small business located in historically underutilized business zones, and firms from underrepresented states [1]. In addition to briefings and one-on-one meetings at several national level conferences, the Department has provided tailored briefings, either at conferences or through webinars, for small technology firms in more than half of the 27 underrepresented states as identified by the Small Business Administration (SBA). Regular updates on upcoming events, outreach, and program information reach an even wider audience through the DoD SBIR/STTR listserv, which has more than 12,000 subscribers, and social media interaction through Twitter and Facebook.

OSBP has worked with DoD leadership to establish, develop, and infuse SBIR/STTR objectives into the Department's normal business procedures and processes. We have established working groups, updated DoD policies, created incentives for acquisition program managers, and implemented mechanisms for collecting and tracking data. The following highlight some of our efforts:

- The establishment of the DoD Commercialization Working Group (CWG), comprising of government experts in SBIR commercialization and led by the OSBP "Program Executive Office (PEO) SBIR/STTR," to standardize transition planning tools and processes across the Department focused on increasing the transition rate of SBIR/STTR-developed technologies into programs of record (PoR) and fielded systems.

- The CWG established formal definitions for commonly misunderstood, key commercialization terms such as "transition" and "Phase III work".

- The CWG provides direct support to acquisition PM's in identifying and transitioning SBIR/STTR-developed technologies into PoR or fielded systems.

    - As an example, PEO SBIR/STTR Commercialization is currently working closely with PMs from the Armored Multi-Purpose Vehicle (AMPV) program, the U.S. Army's largest combat vehicle program, to match program capability needs and recently developed technologies under the SBIR/STTR program. The PEO SBIR/STTR manager has

[1] "The 27 states (AK, AR, DC, DE, HI, IA, ID, KS, KY, LA, ME, MO, MS, MT, ND, NE, NV, OK, PR, RI, SC, SD, TN, UT, VT, WV, WY) with the lowest success in the SBIR program..." Small Business Administration, The Small Business Innovation Research (SBIR) & Small Business Technology Transfer (STTR) Program Interagency Policy Committee Report - SBIR Outreach (draft), May 2014, 8

participated in the AMPV's Defense Acquisition Board (DAB) meetings to provide direct input into their acquisition strategy.

- Inserted into Interim DoD Instruction 5000.02, "Operation of the Defense Acquisition System," requirements for acquisition PMs to establish goals and incentives that increase transition of SBIR/STTR-developed technologies into PoRs and fielded systems.

Table 2. Milestone and Phase Information Requirements, Continued

INFORMATION REQUIREMENT	PROGRAM TYPE[1]				LIFE-CYCLE EVENT[1,2]								SOURCE	APPROVAL AUTHORITY
	MDAP	MAIS	ACAT II	ACAT III	MDD	MS A	CDD Val	Dev RFP Rel	MS B	MS C	FRP/FD Dec	OTHER		
	NOTES													
SMALL BUSINESS INNOVATION RESEARCH (SBIR)/SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM TECHNOLOGIES	*	*	*	*		*		*	*	*	*		15 U.S.C. 638 (Ref (u))	MDA
	STATUTORY. Program managers will establish goals for applying SBIR and STTR technologies in programs of record. For contracts with a value at or above $100 million, program managers will establish a goal for the transition of Phase III technologies in subcontracting plans, and report the number and dollar amount of contracts entered into for Phase III SBIR or STTR projects. At each milestone indicated, the Program Manager will provide a detailed plan for the use of SBIR and STTR technologies and associated planned funding profile (Phase I, II, and III).													

Additional clarification for SBIR/STTR requirements will be inserted into the final DoD Instruction 5000.02:

- Program managers will establish goals for applying SBIR and STTR technologies in programs of record *and incentivize primes to meet those goals.*
- For contracts with a value at or above $100 million, PMs will establish goals for the transition of Phase III technologies

in subcontracting plans *and require primes* to report the number and dollar amount of Phase III SBIR or STTR contracts.

OSBP, DoD leadership, and SBA collaborated on data collection and reporting requirements:

- A data collection gap analysis was conducted to ensure the required fields were incorporated into the annual reports to Congress. This will ensure data from all thirteen participating DoD Components is collected and consolidated in a timely and efficient manner.
- The Department created standardized templates and documented process timelines for all reporting requirements. This has resulted in complete, accurate, and on-time reports.

All new policies and procedures have been documented and communicated to the relevant SBIR/STTR stakeholders through our annual DoD SBIR/STTR Training Workshop held in June 2014.

In Conclusion

The overall health of the DoD SBIR/STTR Programs has shown tremendous improvement. Process timelines, both internally and with small businesses, have been reduced, payments to small businesses have been accelerated, and targeted outreach has resulted in a small but encouraging increase in proposal submissions from underrepresented states. Department-wide knowledge and collaboration has increased through workings groups, our annual training workshop, and professional workforce development initiatives. Also, implementation of SBIR/STTR policies has increased direct participation in transition activities with PoR. The DoD SBIR/STTR program sparks innovation and develops successful, leading-edge technologies to support the warfighter. It is critical that we continue to leverage the robust potential available in our nation's small businesses.

Once again, I appreciate this opportunity to testify on behalf of the DoD SBIR/STTR program.

Implementation Complete	
Section	Title
5101	Extension of Termination Dates
5102	SBIR and STTR Allocation Increase
5103	SBIR and STTR Award Levels
5104	Agency and Program Flexibility
5105	Elimination of Phase II Invitations
5106	Pilot to Allow Phase Flexibility
5107	Participation by Majority-owned Multiple Venture Capital Firms
5108	Special Acquisition Preference
5109	Collaborating with Federal Labs
5110	Notice Requirement
5111	Additional SBIR/STTR Awards
5121	Technical Assistance for Awardees
5122	Commercialization Readiness Program at DoD
5125	Definition of Phase III
5126	Shortened Award Decision Period
5131	Steamlining Annual Evaluation
5132	SBIR Data Collection from Agencies
5133	STTR Data Collection from Agencies
5136	Accuracy in Funding Base Calculations
5137	Evaluations by National Academies
5138	Technology Insertion Reporting
5139	Intellectual Property Protections
5140	Consent to Release Information
5141	Pilot for Administrative Funding
5142	GAO Study of Venture Capital
5143	Reducing Fraud, Waste, and Abuse
5144	Simplified Paperwork Requirements
5162	Competitive Selection Procedures
5164	Limitations on Pilot Programs
5165	Commercialization Success
5166	Publication of Certain Information
5167	Report on Manufacturing Activities
5168	Stimulate Competitive Research

Figure 1. 2011 SBIR/STTR Reauthorization Act section completion

Testimony Before the
Committee on Small Business
U.S. House of Representatives

Statement for Hearing entitled
"Oversight of the Small Business Innovation Research and Small Business Technology Transfer Programs—Part II"

Statement of
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National Institutes of Health
U.S. Department of Health and Human Services

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Good afternoon, Chairman Graves, Ranking Member Velazquez and Members of the Committee. My name is Dr. Matthew Portnoy and I am the Director for the Division of Special Programs within the Office of the Director's Office of Extramural Research at the National Institutes of Health (NIH), and the Coordinator for the SBIR and STTR programs NIH. Thank you for the opportunity to discuss the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs at the NIH, and the role they play in stimulating innovation and our economy. I would like to note that my remarks will primarily focus on NIH because our agency represents 98 percent of the Department's programs, however my office coordinates closely with the Centers for Disease and Control and Prevention, the Food and Drug Administration and the Administration for Children and Families, our sister agencies that also fund SBIR and STTR programs. Among the 11 Federal departments and agencies that participate in these programs, the NIH is one of the largest funders of this program, and the largest Federal supporter of biomedical research. The SBIR/STTR programs continue to be critical to feeding the innovation pipeline that promises to deliver the medical advances of tomorrow and have complemented NIH's mission to advance science while bringing new health care solutions to the public.

IMPORTANCE OF THE SBIR/STTR PROGRAM AT NIH: IGNITING IMAGINATIONS AND SPURRING NEW DISCOVERIES

The NIH SBIR/STTR programs are ideally suited for creating research opportunities for U.S. small businesses to stimulate technological innovation. Part of a complex innovation ecosystem, these programs provide dedicated funding for U.S. small businesses to conduct early-stage research and development (R&D) to explore the feasibility of innovative ideas that may eventually result in products or services that will lead to better health for everyone. The NIH SBIR/STTR programs are one means by which NIH Institutes and Centers (ICs) accomplish their R&D objectives. A key feature that sets SBIR/STTR apart from other NIH programs is a focus on commercialization of the results of research. Thus, the programs serve to supplement the more basic and applied research programs of NIH.

TYPES OF RESEARCH NIH SUPPORTS UNDER SBIR/STTR

Examples of the types of research that NIH supports through the SBIR/STTR programs include, but are not limited to: drug discovery, drug and pharmaceutical development, medical devices, biosensors, nanotechnologies, proteomics, imaging, bioengineering, behavioral research, health services, and other technologies that enhance health, lengthen life, and reduce illness and disability. Researcher-initiated ideas are the cornerstone of the NIH research portfolio, including projects supported by the SBIR/STTR program. Thus, while we solicit projects on specific topics, we primarily encourage small businesses to propose their own innovative research ideas that are relevant to our mission as a way of tapping those closest to the market trends and needs to drive innovation.

NIH SBIR/STTR PROGRAM REAUTHORIZATION IMPLEMENTATION OVERVIEW

I am pleased to share with you today that the implementation of the many changes included in the SBIR/STTR Reauthorization Act of 2011 are completed or nearly completed at NIH. I will now provide you with a brief update on some of our work to date.

SBIR/STTR Funding: In accordance with law, the NIH increased its set-aside for the SBIR and STTR programs to 2.8 and 0.40 percent, respectively, of its extramural research and development budget in Fiscal Year (FY) 2014. Since the reauthorization, the overall budget for the programs has increased from $680 million in FY 2011 (pre-reauthorization) to the current FY 2014 minimum set-aside of $758 million. That is an increase of $78 million that are available to small businesses working in many different technology areas across the country. Throughout, NIH and DHHS continue to meet and exceed the required set-asides each year, as found by two recent GAO reports. At the same time, however, the number of SBIR/STTR applications was on a downward trend during FYs 2012 and 2013. The FY 2013 SBIR award success rate, the percentage of reviewed grant applications that receive funding, the most recent year we have full data, for SBIR programs was 13 percent for Phase I and 33 percent for Phase II. The FY 2013 combined award success rate for the SBIR and STTR programs, all phases was at 16.3 percent.

Increased Outreach Efforts: We have bolstered and diversified our outreach efforts to key stakeholders within the small business community. We are partnering and coordinating with the NIH Institutional Development Award (IDeA) program[1], as required under the reauthorization, to reach underserved small businesses in IDeA states, increasing outreach to women-owned and small disadvantaged businesses, collaborating with more state-based economic development centers to deliver regular series of webinars educating entrepreneurs and small businesses new to the programs about the range of opportunities, and using social media to further engage small businesses. We have also done a tremendous amount of work to educate those impacted directly or indirectly from reauthorization changes through pre-submission webinars and large-scale messaging. Our data show that fully one-third of our applicants and awardees are new each year. Taken together, we believe we are reaching more future applicants and have more effective outreach based on the positive feedback we receive following each outreach event.

Reporting: The reauthorization also called for a number of new reporting requirements. During the past two years, our team held weekly meetings with numerous business units both inside and outside NIH including Small Business Administration (SBA), and stakeholders. From these meetings, we developed policies and processes to implement the reporting requirements of the reauthorization. This required making changes to a deeply integrated and com-

[1] The Institutional Development Award (IDeA) program broadens the geographic distribution of NIH funding for biomedical and behavioral research. See more at: http://www.nigms.nih.gov/Training/IDeA/Pages/default.aspx.

plex NIH system that includes almost two hundred other funding mechanisms, and the recording and monitoring of information on tens of thousands of new awards annually. Thus you can imagine that any change, no matter how small, is far reaching and takes time to implement correctly and appropriately.

SBIR Direct Phase II Pilot and Switching Between Programs[2]*:* These two programmatic changes in particular represented a substantial effort on our part. This past February, we publish a new SBIR Direct Phase II Pilot program funding opportunity announcement, allowing for the first time companies that have established scientific feasibility with non-SBIR/STTR support to bypass the need to apply for Phase I and compete for Phase II funding directly. We received the first round of applications in April 2014 and expect to make first funding decisions in early FY 2015. We will continue to monitor closely the impact of this pilot on our overall success rates. Let me also make an important point about this pilot program. All Direct Phase II applications go through the exact same rigorous peer review process as all other SBIR/STTR applications. We have issued guidance to NIH scientific review officers, grants management officers, and others directly 'touching' these applications and continue to work with other key stakeholders to ensure consistency in review and funding decision processes. To that end, we have made the necessary systems modifications to be able to track these applications separately from regular Phase II and Fast Track awards for reporting and analysis purposes. Similarly, our NIH system is now able to accept applications that switch programs from STTR to SBIR or vice versa at Phase II or Phase IIB (our second, sequential Phase II) of the program. And we continue to conduct rigorous outreach to inform our stakeholders of these new opportunities.

12-Month Award Notification: Earlier this year we have started to notify all applicants of our intent to fund or not to fund their application in compliance with the new requirement to do so within twelve months.

Venture-backed Small Businesses: In 2013, NIH exercised the authority to allow small businesses that are majority owned by multiple venture capital companies, hedge funds and private equity firms to apply for SBIR funding. We received the first applications in late FY 2013 and have made the first award in FY 2014. As in the previously mentioned changes, we worked closely with our information technology specialists to build in the capability to separately track the amount of funding going to these projects for reporting purposes. The current demand for this flexibility is low and we will be monitoring it closely over time.

Shorten Time to Award: Perhaps the most dramatic change the NIH will be deploying soon is the requirement to reduce the time it takes to award funding to our small business applicants, an objective to which we are strongly committed. In the past year we

[2] The NIH Published the following Notice, NOT-OD-14-048, on February 5, 2014: NIH Implements Option for Applicants to Switch between the SBIR/STTR programs and the SBIR Direct to Phase II pilot of the SBIR/STTR Reauthorization Act of 2011—See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-048.html

have evaluated every detailed aspect of the life cycle of an application from the time it first arrives at NIH to the time it is awarded. We have made significant progress and are working to identify a new model that we believe will first and foremost benefit small businesses while at the same time maintaining the meritorious nature of our mandated two-tiered peer review process and meeting congressional expectations with full support of NIH Director Dr. Francis Collins.

Administrative Funding Pilot: NIH is grateful for the financial and human resources support provided through the administrative fund pilot authority to enhance our management of the SBIR/STTR programs in new and better ways. These funds, while currently temporary, have been critical so far in a number of areas across the entire Department. In my immediate office, we have been able to hire a dedicated statistician focused on programmatic analyses and helping us meet existing and new reporting requirements. We also hired a communications specialist now largely overseeing our outreach efforts and expanding our social media capabilities, especially targeting IDeA states, women-owned and small disadvantaged businesses. NIH has begun proactively delivering a variety of webinars about the SBIR/STTR programs and drawing large numbers of attendees. Across the NIH, a number of ICs have used the funds to hire new program support staff to help with outreach, reporting, and work on improvements in their IT infrastructures for more efficient evaluation and management of their award portfolios. Our central SBIR office also issued a contract to help us redesign our NIH SBIR/STTR website; build in additional IT functionality into our Performance Outcomes and Data Systems (PODS) database that integrates all award data, success stories and other program data to now store the commercialization outcomes data that will be linking to the new SBA commercialization database; and create other centralized internal and external web-based tools for our program managers and the small business applicants and awardees. These funds have been used across NIH to increase outreach to underserved SBIR and STTR communities and to make improvements in our processes, all to the benefit of the small business community. These activities would not have been possible without the additional funds under the pilot.

PROGRAM FLEXIBILITY IS KEY: ONE SIZE DOES NOT FIT ALL

We are eager to see the effects of these many changes in the coming years and are continually focused on ways to address the needs of a diverse small business community navigating through a complex regulatory landscape, ever-changing private sector risk appetite and expectations, and continually rising cost of R&D. I would stress that NIH attributes the success and effectiveness of its programs to several factors, the most significant of which is a flexible and proactive approach that adapts to the changing nature of biomedical and behavioral research while maintaining a highly competitive and effective program.

Examples of program flexibility include the ability to propose research projects in fields that have the most biomedical potential; the ability for an applicant to resubmit an unfunded application;

and the ability to fund Phase I and Phase II awards at appropriate budgets that may exceed the established guidelines if the science proposed warrants such an exception to ensure successful outcomes. The NIH Phase II average award size in FY 2013 was $1.3 million for SBIR and $1.1 million for STTR. Biomedical research presents a unique set of challenges that require appropriate resources to commercialize the next set of discoveries.

The NIH also has a suite of funding gap and technical assistance programs to help companies accelerate their projects forward into the next stage of R&D development and help them navigate the period between discovery and commercialization. Thus we help companies grow into sustainable businesses and leverage our investments in the long run.

CONCLUSION

In conclusion, I want to re-emphasize that flexibility is critical at a time when science is changing rapidly, becoming more complex, more interdisciplinary, and resource intensive. The SBIR program seeks to fund the most scientifically promising projects for which private and public funds are not traditionally available. Also, as a responsible steward of taxpayers' dollars, we strive to leverage NIH's portfolio across the biomedical enterprise. NIH SBIR projects are stories of discovery. One example is IntraLase Corporation from Irvine, California which developed the ultra-fast femtosecond (FS) laser for use in ophthalmology with more than $400,000 in NIH SBIR funding from the National Eye Institute. The company was acquired in 2007 for $877 million by Advanced Medical Optics, a division of Abbott, who developed it into today's LASIK technology and also uses it for advanced corneal surgery procedures. And we are committed to doing what we can to ensure that the small businesses we fund today may become the Marteks, Medlmmunes, and Abbotts of tomorrow. These companies all received SBIR funding in their early stages and went on to create thousands of new jobs, deliver products that are making real and significant impact on the lives and health of millions of people, and became household names across our country.

This concludes my statement. Thank you for your attention and I look forward to answering any questions you may have.

SBA responses to Questions for the Record: Rep. Velázquez July 23, 2014

According to data on sbir.gov, from 1996 to 2013, Women-owned firms' share of SBIR awards, by value, decreased from 9.8 percent to 6.4 percent, a decline of 35 percent. In the same period, award shares for minority-owned firms fell from 8.3 percent in [sic] to 2.6 percent, a decline of 70 percent. Why are women and minorities receiving a declining level of funding through these programs?

a. Why aren't agencies able to be more successful in this area?

SBA response:

The data on SBIR.gov that has been officially verified and cleared for public review is only the annual report data which is current through fiscal year (FY) 2011.

The information and data currently available on SBIR.gov for FY2012 and 2013 is incomplete as it only shows data as inputted by the companies and has not yet been fully verified by SBA.

In addition, SBA is currently collecting all of the historical information from the participating agencies to be uploaded into the new commercialization database which will provide a fully synchronized and more comprehensive view of SBIR/STTR commercialization data. This will provide the complete data for any analysis. SBA intends for the commercialization database to be available to the public by the end of this calendar year.

We are in the process of getting clearance of the 2012 Annual Report. This report shows a preliminary uptick in the number of awards made to Women and Minority-owned firms. SBA anticipates that the FY2012 data will soon be publicly available.

SBA is currently coordinating initiatives at all 11 SBIR/STTR participating agencies focusing on improving the outreach to and program participation of woman-owned small businesses and socially and economically disadvantaged small businesses.

These efforts include our continued collaboration, internally, with SBA's Office of Entrepreneurial Development, Office of Women's Business Outreach, and National Women's Business Council. Additionally, we are now collaborating with other federal agency partners such as the US Department of Commerce's Office of Innovation & Entrepreneurship and US Patent & Trademark Office, US Agency for International Development's Global Development Lab, and The National Endowment for the Arts and also non-federal organizations such as National Society of Black Engineers, Society of Women Engineers, National Council of Entrepreneurial Tech Transfer, Puerto Rico Science Trust, XPrize Trust, and the American Association for the Advancement of Science-Lemelson Foundation Invention Ambassador program.

2. California and Massachusetts together win 35 percent of awards through the SBIR program. Meanwhile, states like Oregon, New Hampshire, and Arizona receive less than 2 per-

cent of awards. The top ten states receive almost 70 percent of awards. This pattern has been consistent for most of the programs' duration. Why aren't agencies making progress to geographically diversify the program?

SBA response:

The historical concentration of awards in certain states is partially due to the concentration of research institutions, universities, entrepreneurial activity, capital and infrastructure in those specific states. Those general components are needed for STEM-driven commercially viable innovation. This type of ecosystem is critical for the early-stage, high risk technology being developed via the SBIR/STTR program; therefore, a concentration of awards is seen where those ecosystems are more robust.

The SBIR/STTR programs have always limited their award selection to the following statutory criteria to: (1) scientific and technological merit and (2) potential for commercialization. To provide as much assistance as possible to states with fewer awards, SBA and the participating agencies are supporting outreach efforts in these states to help companies learn about the programs, prepare proposals, and access the relevant local business assistance infrastructure. A few examples of our recent outreach efforts include SBIR and STTR awareness events with STEM professionals and entrepreneurs in San Juan, Puerto Rico; Boise, Idaho; Sioux Falls, South Dakota; and Providence, Rhode Island.

In addition, 8 Agencies have requested administrative funding to increase their marketing and outreach efforts to underserved states.

3. According to data from sbir.gov, some companies have won hundreds of awards for over $100 million. In many instances, individual companies have won more in SBIR funding than many states—often times winning more than multiple states combined. We have heard that there are too few companies to apply or that certain agencies have developed strong relationships with certain companies. Why do you think that the same handful of companies are able to win the most awards in these program year after year?

a. Is the ability of so few companies to receive so many awards year after year good for the program? Why or Why not?

SBA response:

Although the issue of multiple award winners has often been raised, and until reauthorization there was never a limit placed on the number of awards a firm may receive from the SBIR/STTR programs, we have now implemented the commercialization benchmarks on number of awards a firm may receive before being placed on suspension if they go over the limit for Phase 1 or Phase 2 award. In addition, the proposal review and award selection processes used are quality-driven, require a high level of integrity, and are successful at selecting high quality projects. Roughly about one-third of SBIR/STTR awards go to first-time winners. Some of the

awardee firms that win multiple awards provide much needed competition within the Federal procurement market for high risk technology development.

4. In your testimony, you stated that a quarter of the value of SBIR and STTR awards in 2012 went to women-owned, minority-owned, or HUBZone located small businesses. According to data on SBIR.gov, however, the programs awarded a dollar value equal to 7.4 percent to women-owned, minority-owned, and HUBZone businesses in 2012. Which data source is correct, your testimony or the sbir.gov website?

a. Please explain this discrepancy between the data in your testimony and the sbir.gov website.

SBA response:

The testimony provided was accurate and reflected information that is not currently available on SBIR.gov. The data that is publicly available on SBIR.gov only reflects annual report data that has been verified through FY 2011. SBA is currently collecting historical information from the agencies and also their award data for FY 2012 and FY 2013. Once this data is verified and analyzed it will be publicly released and SBIR.gov will be updated.

5. Do you believe that there is enough high-quality small business research to justify the increases in the set-aside percentages contained in the 2011 reauthorization?

a. Would an annually negotiated agency goal for small business research—similar to contracting goals—be a better mechanism?

SBA response:

Based on a study conducted by R&D Magazine [1], over 25% of innovative R&D in the U.S. originates with small business concerns funded by the SBIR/STTR programs. There are sufficient numbers of small business research firms to justify the increases in the programs' set-aside percentages. Recently there have been a number of articles and Op-Eds [2] indicating additional laudatory support for the program from notable technologies and entrepreneurs [3].

SBA does not believe an annually negotiated agency goal would serve as an effective mechanism to fund the SBIR and STTR programs. The historical success of these programs is, in no small part, due to the fact that agencies are required, by law, to use a specified minimum portion of their extramural research/research and development (R/R&D) budgets for these programs. Without this clear statutory requirement, it is unlikely that federal agencies would provide adequate support for small business-lead innovation on a consistent basis. Although the language in the statute is clear that the set-aside percentages are minimums, most participating agencies treat them as target amounts that are rarely intentionally

[1] *http://www.itif.org/files/Where_do_innovations_come_from.pdf*
[2] *http://www.entrepreneur.com/article/236008*
[3] *http://www.business2community.com/startups/countrys-best-kept-secret-startup-seed-funding-0958250*

exceeded. And this tendency persists despite the notable success of the programs.

The SBIR/STTR programs are designed to help seed-finance next generation technology development for federal government needs and be applicable for mainstream commercial needs, where possible. For example, 3D Printing is an industry which can be traced back to the U.S. National Science Foundation's SBIR program. Another example is the biotechnology industry. Many titans of that industry, such as Biogen (now Biogen IDEC Incorporated), Genentech (now part of F. Hoffman-La Roche AG and Amgen Incorporated) got their start in the 1980's and 1990's with scientists in their employ receiving SBIR grants from the National Institutes of Health.

6. SBA's budget submission for FY 2015 revealed that the agency was not requesting funds for FAST (on Table 5, page 20 of their submission) a program that provides outreach to underserved areas. Why did SBA not seek funding for FAST?

a. Given the low levels of women and minorities and the geographic concentration, should FAST be expanded?

SBA response:

The program was initially authorized at $10 million per year; however it has never been funded at that level. Congress has funded the program with approximately $2M in appropriations annually. In FY2016, Budget submission SBA requested additional $2M in appropriations to support the program. The request for the additional funding is to provide more training to states to encourage more participation in the SBIR/STTR programs.

7. You state in your testimony that SBA is developing a new commercialization database so the private sector can find research opportunities. How do you plan to disseminate this information to the private sector?

SBA response:

The new commercialization database will be used to evaluate the effectiveness of the SBIR and STTR programs. The sensitive elements of the data are collected from awardee firms and treated as proprietary. The proprietary data is not made public or shared with other companies, without the consent of the company. Non-confidential elements of the data will be publicly available on sbir.gov and can be used to showcase a particular SBIR/STTR awardee's award history in specific topical areas of interest by the awarding agency. We also plan to publish a running roster of success stories that will include but not be limited to Tibbetts Awards winners and SBIR/STTR Hall of Fame Inductees.

8. While some job creation data does exist for SBIR/STTR, it is often the result of ad hoc reports produced by agencies. How difficult would it be for SBA to collect this information?

SBA response:

Some employment data is being collected from awardee firms as part of the SBA commercialization database. This data, however, does not correlate directly with job creation and surveying this type of data can be a costly laborious process that would impact small businesses that are already focused on competing in a globally competitive marketplace.

CHARRTS No.: HSBC-01-001

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congressman Graves

Witness: Director (OSBP) Gudger

Question: #1

Utilization of SBIR technologies

Question: The Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics approved Department of Defense (DOD) Instruction 5000.02. This instruction requires Program Managers to set goals for utilization of Small Business Innovation Research (SBIR) technologies. How is your office measuring implementation of these goals?

Answer: Initially, DoD is measuring implementation of goals by participating in select Program-of-Record (PoR) Overarching Integrated Product Team (OIPT) meetings and Defense Acquisition Board (DAB) Milestone reviews to monitor Acquisition Strategy documentation. A centralized database is being developed to provide a reporting mechanism to automate tracking of goals and incentives by program.

CHARRTS No.: HSBC-01-002

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congressman Graves

Witness: Director (OSBP) Gudger

Question: #2

Transitioning SBIR technology into acquisition programs

Question: In your written statement and comments at the hearing, you indicated that DOD has created mechanisms and incentives for acquisition program managers and prime contractors to increase SBIR technology transition into acquisition programs of record and fielded systems. Please provide the following information:

a. What specific actions have been established in DOD policy and procedures since the 2012 reauthorization of SBIR to increase transition?

b. What major defense acquisition programs of record have implemented transition goals and incentives in 2013 and 2014?

c. How are goals and incentives specified in these programs?

d. What incentives have these programs used?

Answer:

a. Specific goals and incentive requirements for acquisition program managers have been inserted into the Interim DoD Instruction 5000.02, "Operation of the Defense Acquisition System," (November 25, 2013). Expanded guidance has been added to the corresponding Defense Acquisition Guidbook (DAG). These resources were recently briefed by senior subject matter experts at our 2014 SBIR/STTR Annual Training Workshop, attended byover 300 DoD acquisition, contracting and technical personnel.

b. All major defense acquisition programs of record are required to comply with the DoDI 5000.02 for new contracts. The requirement does not apply retroactively to existing contracts.

c. Goals and incentives are determined for individual programs according to acquisition phase and market research of technological opportunities.

d. All incentives permitted by the DFARS will be allowed. Incentives do not apply retroactively, but will be included in new contracts.

CHARRTS No.: HSBC-01-003

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congressman Graves

Witness: Director (OSBP) Gudger

Question: #3

Collection and tracking of SBIR technology transition data

Question: You also indicated that a number of steps have been taken to improve the collection and tracking of SBIR technology transition data and that the department is meeting all reporting requirements. Please provide the following information:

a. What are the specific actions DOD implemented to improve transition data?

b. What data system is being used to track transition outcomes?

c. How has the department addressed the data quality issues GAO highlighted in its report GAO–14–96 (Dec. 2013)?

d. What are the number and percentage of SBIR Phase II projects that transitioned into acquisition programs of record or fielded systems in 2013?

e. Was this information included in the department's annual reporting to SBA?

Answer:

a. The current reporting uses existing systems that include the Company Commercial Report and information obtained from individual Military Service and Component databases. The specific actions DoD implemented to improve transition data include an evaluation of limitations in the current reporting systems. A concept development for an entirely new system is ongoing. Current systems are insufficient to collect all of the data.

b. The current system to track transition outcomes include the Company Commercial Report and information obtained from individual Military Department and other DoD Component databases.

c. The department has evaluated the limitations in the current reporting systems, and is in concept development of an entirely new system.

d. OSBP currently requests Phase III data from SBIR and STTR firms. This data is self-reported and captures both DoD and non-DoD Phase III funding. Approximately $1.1 billion of DoD Phase III funding was reporting in FY 2013. This funding may come from laboratories and other DoD funding sources, in addition to programs of record and fielded systems. New reporting mechanisms to capture the number and percentage of SBIR Phase II projects that have transitioned into acquisition programs of record or fielded systems are being developed.

e. Yes, DoD reports all information that is required by SBA in the annual reports.

CHARRTS No.: HSBC-01-004

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congressman Graves

Witness: Director (OSBP) Gudger

Question: #4

Implementation of certain legal provisions

Question: During your oral testimony, you stated "... the reauthorization which has 41 provisions, which 34 of those applied directly to the Department of Defense, we have successfully implemented all 34 of those as of today." Could you please elaborate and explain specifically how you have implemented the provisions of the law contained in Sections:

a. 5106—Please outline each step taken to utilize the additional funding provided in this section and what additional activities your office and the individual program managers have been able to exploit.

b. 5108—Please outline the specific incentives utilized by both the DOD and prime contractors to increase transition of SBIR technology.

c. 5122—Please state the goal that has been established that lead to technology transition into programs of record or fielded systems, and how that goal has been implemented and disseminated to the DOD SBIR program managers.

d. 5125—Please outline what actions your office has taken to ensure all program managers at the DOD have received instruction on the clarified definition of "Phase III."

e. 5165—Please describe in detail how the DOD is tracking commercialization success between all Phases of the SBIR program, how the DOD is working with the SBA to ensure accuracy with the commercialization success regulations published by the SBA, and please list any companies that have failed to meet proscribed commercialization benchmarks.

Answer:

a. Section 5106, which amended 15 U.S.C. 638, provided additional program flexibility, but no additional funding to implement the pilot program. DoD is conducting a pilot program with Defense Advanced Research Projects Agency (DARPA) regarding direct Phase II awards. Based on the initial DARPA pilot program success and lessons learned, DoD OSBP is in the process of opening up this pilot to other DoD Components. No additional funds were required for implementation.

b. Section 5108 does not mention incentives. Regarding the SBIR incentives required by Section 5122, all incentives permitted by the DFARS will be allowed. Incentives do not apply retroactively, but will be included in new contracts.

c. The department-wide goal is to increase the use of SBIR technologies in programs of record. The individual program goals are determined according to acquisition phase and market research of technological opportunities. The goal has been communicated to the DoD SBIR program managers in written guidance, monthly meetings, and at the 2014 Annual SBIR/STTR Training Workshop.

d. DoD has updated the definition of "Phase III" on all DoD SBIR websites, published information, program documentation, and department wide training materials. It was also briefed by DoD at the 2014 Annual SBIR/STTR Training Workshop.

e. DOD tracks commercialization success between all Phases of the SBIR program through our DoD SBIR/STTR Awards database and the Company Commercialization Report (CCR) database. DoD works directly with SBA to verify accuracy with the commercialization success regulations published by the SBA each year. The official list of companies that have failed to meet prescribed commercialization benchmarks is maintained at SBA.

CHARRTS No.: HSBC-01-005

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congresswoman Velázquez

Witness: Director (OSBP) Gudger

Question: #5

SBIR VC-backed firms

Question: According to sbir.gov, the only agency currently permitting VC-backed firms to participate in their SBIR program is the NIH. Prior to the rule change in 2003, venture-backed firms participated in DOD's SBIR programs regularly. Given this, why hasn't DOD or any of their military agencies taken advantage of this provision allowing VC-backed companies to regain access to the DOD's SBIR program?

Answer: VC-backed firms are currently authorized to participate in the DoD SBIR program. The only restriction is related to majority-owned venture capital operating companies (VCOC). DoD already receives more quality/competitive proposals from independ-

ently owned small businesses, both VC-backed and non VC-backed, than we can fund.

CHARRTS No.: HSBC-01-006

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congresswoman Velázquez

Witness: Director (OSBP) Gudger

Question: #6

3 percent of SBIR funds used on administration

Question: The 2011 reauthorization allows for up to 3 percent of SBIR funds to be used for program management and administrative purposes, including outreach. Is DOD using the full 3 percent available? a. What has this additional funding allowed DOD to do that it would not have been able to do otherwise? b. Are you concerned that this takes money away from small business awards?

Answer: No, we are not using the full 3 percent.

a. The primary areas that additional funding has allowed DoD to expand the most have been related to commercialization and outreach. The extra funding has allowed the DoD Components that did not already have Technical Assistance Programs to establish them to help increase commercialization efforts. The funding has also been used to expand outreach activities and efforts specifically to improve marketing SBIR/STTR program information to underrepresented States and categories.

b. The administrative funding allows DoD to pursue initiatives that directly benefit all small businesses participating in the DoD SBIR/STTR Program. The support services and tools being developed and implemented with the administrative funding provide a greater value to the small businesses in the areas of commercialization, outreach, and streamlining than the small businesses could leverage on their own. Any administrative funding not used for this purpose is used to fund additional SBIR projects.

CHARRTS No.: HSBC-01-007

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congresswoman Velázquez

Witness: Director (OSBP) Gudger

Question: #7

SBIR phase III awards

Question: The 2011 reauthorization legislation focused greatly on commercialization. One provision requires agencies to issue Phase III awards relating to technology, including sole source awards, to the SBIR and STTR award recipients that developed the technology. Has your agency made any such awards?

Answer: DoD has made nearly 3,000 Phase III awards, totaling nearly $4 billion in non-SBIR funding, since the 2011 reauthorization.

CHARRTS No.: HSBC-01-008

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congresswoman Velázquez

Witness: Director (OSBP) Gudger

Question: #8

SBIR/STTR commercialization frequency

Question: Companies that frequently win SBIR and STTR awards without commercializing their research have long been a concern. In terms of the application process, how does DOD view repeated failures by SBIR/STTR companies to commercialize their research?

Answer: Commercialization is used as an evaluation factor for small business concerns that have previous DoD SBIR/STTR experience as noted in the latest DoD SBIR solicitation (14.3). Per Section 4(a)(3) of the SBA SBIR Policy Directive (updated February 24, 2014), small businesses that have an unacceptably low rates of transitioning from Phase I to Phase II and from Phase II to Phase III are restricted from receiving a Phase I awards for one year.

CHARRTS No.: HSBC-01-009

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congresswoman Velázquez

Witness: Director (OSBP) Gudger

Question: #9

SBIR and STTR in subcontracting plans

Question: You testified that DOD is going to specifically include goals for SBIR and STTR technologies in subcontracting plans and require prime contractors report on this performance. In the event that a prime does not meet a goal, what will be the repercussions?

Answer: Currently, DoD is proposing language for the Defense Federal Acquisition Regulation Supplement (DFARS) requiring SBIR and STTR goals in contracts greater than $100M. DoD intends to encourage contracting officers to include past performance in meeting SBIR and STTR goals as a source selection evaluation factor.

When SBIR transition plans and goals are included in contractors' subcontracting plans, compliance will be monitored in accordance with FAR 19.706, which directs the contract administration office to track whether the contractor is meeting the subcontracting goals, whether the contractor is expending the efforts promised in the subcontracting plan, and, if the contractor is not meeting a goal, whether it is making a good faith effort to comply. The contract administration office also is instructed by FAR 19.706 to maintain documentation of the contractor's performance and compliance with subcontracting plans from previous contracts. Additionally, in Defense contracts, DFARS 219.706 directs the small business specialist to support the administrative contracting officer in evaluating a contractor's compliance with its subcontracting plan.

CHARRTS No.: HSBC-01-010

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congresswoman Velázquez

Witness: Director (OSBP) Gudger

Question: #10

Multiple phase II grants

Question: The reauthorization ensured that federal agencies can continue to award multiple Phase II grants. While this may reduce the number of awards, it may increase commercialization. How is this affecting DOD's SBIR program?

Answer: The limit of two Phase II awards that can be given for any particular topic can occasionally restrict very promising innovations from being widely utilized throughout the Department or by other Federal agencies.

CHARRTS No.: HSBC-01-011

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congresswoman Velázquez

Witness: Director (OSBP) Gudger

Question: #11

Commercialization pilot program made permanent

Question: The 2011 reauthorization made the commercialization pilot program at DOD permanent. This initiative allows DOD to use 1 percent of SBIR funds for commercialization purposes. Is this level sufficient to accomplish the commercialization objectives set out by the law?

Answer: The 1 percent is being used, in addition to a portion of overall administrative funding, to meet the objectives of the program. It is not clear at this point whether these resources will be adequate.

CHARRTS No.: HSBC-01-012

Hearing Date: July 23, 2014

Committee: HSBC

Member: Congresswoman Velázquez

Witness: Director (OSBP) Gudger

Question: #12

Small business set-asides

Question: Do you believe that there is enough high-quality small business research to justify the increases in the set-aside percentages contained in the 2011 reauthorization? a. Would an annually negotiated agency goal for small business research—similar to contracting goals—be a better mechanism?

Answer: Due to the number of high quality of SBIR and STTR proposals received, the process for determining annual SBIR/STTR research areas is a very competitive process. The increase in the set-aside has allowed DoD to expand investments in research areas and to invest in additional DoD high, priority research areas.

a. The current mechanism ensures full expenditures of the SBIR/STTR funding set-aside are achieved. A percentage of set-aside calculated across the top line RDT&E budget would ensure a more accurate and timely calculation of the minimum expenditures.

Statement for the Record

Rep. Steve Chabot

House Committee on Small Business

"Oversight of the Small Business Innovation Research and Small Business Technology Transfer Programs - Part II"

7/23/2014

I would like to thank Chairman Graves for holding this installment of the series of hearings on oversight of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs. It is an incredibly important topic that impacts a lot of small businesses across the full spectrum of industries.

Thank you to all panelists for testifying before the committee. My question is for Dr. Portnoy.

Dr. Portnoy, thank you for testifying and thank you for your work at the NIH. It is well understood that the NIH plays a critical role in innovation, by collaborating with the private sector, to help advance therapies and technologies for the American people, and SBIR/STTR grants help stimulate that collaboration.

Ohio, particularly my hometown of Cincinnati, is home to a number of fantastic research institutions, hospitals, and companies that are leading the way in the discovery and development of new therapies and technologies to treat all sorts of diseases.

One particular disease that hits close to home is diabetes, which now impacts 885,000 Ohioans and costs $9.3 billion annually. Nationally, diabetes has an even more traumatic toll, impacting 29 million Americans and costing $245 billion each year. I understand that the NIH, with the support of the Special Diabetes Program, has invested in research institutions, including universities and small businesses, to encourage diabetes innovation.

Could you share with the Committee some of the highlights of this work and how the NIH is prioritizing further private sector involvement in addressing diabetes?

# # #

Answer: The National Institutes of Health (NIH) has and will continue to partner with the private sector to advance innovative research on diabetes and its complications. For example, small businesses have received grants supported by the Special Diabetes Program for research to develop artificial pancreas technologies for people with type 1 diabetes. An artificial pancreas actually would link three technologies: a glucose-sensing component; an insulin delivery device, such as an insulin pump; and a computer that calculates the amount of insulin needed in response to the blood glucose level. This technology holds great promise to help people with

type 1 diabetes achieve recommended levels of blood glucose control associated with reduced risk of long-term complications, while preventing dangerously low blood glucose levels and alleviating patient burden. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), one of NIH's 27 institutes and centers, has supported many aspects of research toward the development of an artificial pancreas, to a large extent through grants to small businesses, for at least two decades. For example, all the current continuous glucose monitoring technologies on the market benefitted from NIH support early in development. Those technologies are currently being used by patients, but are also a major milestone toward developing artificial pancreas systems.

To accelerate progress in this field, the NIH has intensified its artificial pancreas research program with support from the Special Diabetes Program and annual NIH appropriations. Small businesses continue to be an important partner in this research endeavor. For example, Thermalin Diabetes, Inc., in your home state of Ohio, has received funding support from the Special Diabetes Program, as well as from annual NIH appropriations, to develop ultra-stable and ultra-rapid insulin formulations that could be used in long-term implantable insulin pumps, which could potentially be part of an artificial pancreas system. In fact, with support from the Special Diabetes Program, Thermalin is working in collaboration with an academic research center and other small businesses to develop an implantable artificial pancreas system. In this effort, the small business partners develop novel glucose sensors, insulin pumps, and improved insulin formulations, while the academic center conducts pre-clinical and clinical studies. Thus, the research is leveraging the unique expertise of academic and private sector partners to advance artificial pancreas research. Later this fiscal year, the NIH expects to award additional small business grants toward developing artificial pancreas technologies to continue to build on the tremendous progress to date. In addition to research toward artificial pancreas technologies, the NIH has also awarded Special Diabetes Program-supported grants to small businesses to develop new therapeutic and diagnostic tools for diabetic complications, as well as new methods and technologies to identify individuals at risk of developing type 1 diabetes.

Partnership with the private sector has also been critically important in the Special Diabetes Program-supported Type 1 Diabetes TrialNet, which is a major, multi-site, national clinical trials network testing strategies for type 1 diabetes prevention and early treatment. TrialNet regional sites in Cincinnati, other parts of Ohio, and throughout the United States have screened over 100,000 people to identify those at risk of developing type 1 diabetes for enrollment in prevention trials. Improved screening tests developed through research conducted by small businesses, as described above, could help expand TrialNet's screening efforts and make screening less burdensome for families, including those in Ohio served by TrialNet sites. TrialNet also works closely with private partners, receiving support from the JDRF (formerly the Juvenile Diabetes Research Foundation) and the American Diabetes Association, and collaborates with industry on studies aimed at slow-

ing disease4 progression in newly diagnosed patients. TrialNet's prevention efforts are particularly important because the Special Diabetes Program-supported SEARCH for Diabetes in Youth Study, which has a study in Cincinnati and is jointly led by NIH and CDC, has shown that rates of type 1 diabetes are rising in American youth. Thus, research conducted in Cincinnati and throughout Ohio—through small businesses, public-private partnerships, and research institutions—is contributing to defining the extent of the diabetes problem in the United States, testing approaches to stem the disease, and developing innovative technologies to improve the lives of those with type 1 diabetes today.

Questions for the Record from Ranking Member Nydia Velázquez for Dr. Portnoy

1. SBA has approved a waiver for the NIH to exceed the caps on award amounts for specific research topics. What is NIH able to accomplish with these larger award sizes?

a. In the next reauthorization, do you believe that the award amount should be increased further?

Answer: In order to achieve its mission with its SBIR and STTR programs, the National Institutes of Health (NIH) funds projects level deemed appropriate for each specific research study. Biomedical and behavioral research is unique, as: (1) the cost of such research can often exceed the statutory cap, especially when compared with other research and development conducted under the SBIR and STTR programs; (2) projects need adequate funding to move products far enough along for regulatory filings, testing, and approval; and (3) projects need adequate funding to attract third-party funding and partnerships after the SBIR/STTR project period in order to move products along the commercialization path (those projects may ultimately take years and require significant investment).

Underfunding a Phase I, II, or IIB SBIR/STTR project could potentially cause a project to fail and not reach the market.

NIH attributes the success and effectiveness of its SBIR and STTR programs to several factors, the most significant of which is a flexible and proactive approach that adapts to the changing nature of biomedical and behavioral research while maintaining a highly competitive and effective program. Examples of program flexibility include the ability to propose research projects in fields that have the most biomedical potential and the ability to fund Phase I and Phase II awards at budgets that may exceed the established guidelines when the science proposed warrants such a deviation to produce successful outcomes. Between 2009 and 2012, approximately 25 percent of NIH's SBIR funding was spent on the amount exceeding the hard cap established under the recent reauthorization. For example, in FY 2011 Avatar Medical, LLC, from Brooklyn, NY, received a two-year $600,000 Phase 1 SBIR award to develop an injectable HIV vaccine. In FY 2013, the company received a follow-on Phase 2 award for approximately $3,000,000 over three years to further the development of the vaccine. NIH continues to appreciate the flexibility afforded by Congress to tailor its SBIR and STTR programs to the needs of our agency to ensure NIH fulfills its mission and brings life-saving and life-changing technologies to the market.

2. For NIH, the reauthorization established a Phase Zero program to facilitate the proof-of-concept process and accelerate product development. In April, NIH announced that it would implement this through the creation of REACH Hubs. Do these REACH Hubs have any specific outreach targets or goals?

Answer: The NIH Research Evaluation and Commercialization Hubs (REACH Hubs) will foster the development of therapeutics, preventatives, diagnostics, devices, and tools that address diseases within the NIH's mission in a manner consistent with business case development. Each HUB will assemble diverse experts in translational and proof of concept research who have the knowledge required to identify and develop promising early stage technologies in order to accelerate their translation into commercial technologies to enhance human health. Each Hub will focus on research projects that have progressed to a point where a potential commercial product can be envisioned, but additional research and development efforts are required to define the product and demonstrate feasibility as well as proof-of-concept.

REACH Hubs will provide entrepreneurial educational opportunities to academic investigators about the design and conduct of product definition studies and the commercialization processes required for transitioning a technology out of academic labs to the private sector (either as startup small businesses or licensing opportunities). Cross-disciplinary career development, including from science, business, and regulatory perspectives, is highly encouraged to achieve the goal of exposing innovators to the myriad processes required to translate discoveries into marketable products. NIH encouraged the broader investigator community, including those from traditionally under-represented backgrounds, to access forums, seminars, workshops, and related activities to learn about this unique opportunity. NIH is especially interested in promoting participation of organizations from Institutional Development Award (IDeA) states in the REACH Hubs, and encouraged applications from eligible IDeA states as well as outreach from non-IDeA based applicants to existing IDeA programs.

The REACH Hub funding solicitation RFA-OD-14-005 recently closed and applications are currently under review.[1] NIH anticipates making the awards in March 2015.

3. The reauthorization included pilot authority for three agencies - NIH, DOD, and the Department of Education - to make Phase 2 awards to companies that did not receive Phase 1 awards. How will this initiative affect the composition of NIH's SBIR program?

Answer: NIH recently implemented the SBIR "Direct to Phase II" pilot when it published in February 2014 PAR-14-088 SBIR Direct to Phase II funding opportunity program announcement, a three-year pilot with three receipt dates per year.[2] NIH is currently reviewing the first applications, which were submitted in April 2014, with possible awards to be made in FY 2015. At this time, it is too early to know how awards made under this provision will affect the composition of the NIH SBIR program. The NIH SBIR/STTR program office will track and monitor the effect of this pilot on the SBIR program over time.

[1] Complete details may be found at the solicitation posted at: http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-14-005.html.

[2] See http://grants.nih.gov/grants/guide/pa-files/PAR-14-088.html.

4. The set-aside at NIH increased by $78 million this year, but the number of applications was on a downward trend. Do you believe that this lack of competition will reduce the quality of work undertaken in SBIR and STTR?

a. Was the set-aside percentage increased too much or too quickly for agencies and small firms to adjust?

Answer: The NIH SBIR/STTR set-asides have increased by $78 million since the reauthorization went into effect. The number of applications does fluctuate from year to year historically. While the past two fiscal years have seen a downward trend in applications with an overall decline of approximately 1,100 applications, preliminarily, the FY 2014 application numbers are trending up.[3] NIH does not believe there is or will be a lack of competition within the SBIR and STTR programs. The success rates for the programs typically range between 15-20 percent for Phase I and 25-40 percent for Phase II, which is competitive and comparable to other agency success rates. The programs are and remain very competitive, and the quality of research conducted by SBIR and STTR firms remains high.

5. Do you believe that there is enough high-quality small business research to justify the increases in the set-aside percentages contained in the 2011 reauthorization?

a. Would an annually negotiated agency goal for small business research - similar to contracting goals - be a better mechanism?

Answer: NIH does not believe there is or will be a lack of competition for the SBIR and STTR programs. These programs are and remain very competitive and the quality of research conducted by SBIR and STTR firms remains high. NIH supports the historical set-aside model as it allows for program stability and for program planning from year to year given that awards are multi-year.

6. The reauthorization allowed VC-backed companies to be eligible for 25 percent of SBIR funding at NIH. While it is still very early in the process, do you believe that the 25 percent limit is too high, too low, or just right?

Answer: NIH agrees that it is every early in the implementation of the VC provision, where NIH may award up to 25 percent of its SBIR funding to VC-backed companies. NIH implemented the ability for VC-backed companies to apply to the SBIR program in mid-FY 2013. The first awards were recently made to VC-backed companies. The NIH SBIR/STTR program office will track and monitor participation by VC-backed companies and its effect on the SBIR program over time.

7. Under the reauthorization, agencies have to "opt-in" and justify their decision to allow VC backed small businesses to participate in their SBIR program. Is this becoming a roadblock to VC-backed participation in the program?

[3] NIH received FY 2011 6,415 SBIR and STTR applications, 5,847 applications in FY 2012, and 5,290 applications in FY 2013

Answer: No, this is not a roadblock to VC-backed small business participation in the SBIR program. The opt-in was an agency responsibility, which NIH completed in FY 2013.

8. Given the changes from the 2011 reauthorization, why do you believe that VC-backed company participation in NIH's SBIR and STTR programs is so low?

Answer: When NIH implemented the VC provision in mid FY 2013, we employed a variety of means of informing the small business community about this new flexibility. This includes:

- Modifying all of our SBIR solicitations issued after implementation of the revised VC eligibility;
- Updating the NIH SBIR website and the SBIR.gov website, via SBA, to indicate the implementation;
- Notifying the small business community, including SBIR advocates, state-level economic development groups that support SBIR/STTR, and many other relevant communities, through email about the new flexibility through our listserv, which contains more than 16,000 subscribers;
- Requesting NIH Institute and Center SBIR/STTR Program Managers to reach out to their communities and constituencies regularly;
- Tweeting about the VC provision from our @ NIHsbir Twitter handle that has more than 1,000 followers;
- Conducting Pre-Submission webinars to an audience of more than 1,000 attendees and archived for repeat viewing discussing this provision and other new flexibilities implemented;
- Adding slides about the VC provision to all NIH standard SBIR slides decks for all our webinar and in person outreach events including dozens of events per year across the country; and
- Discussing this provision at SBIR National Conferences, NIH Annual SBIR/STTR Conferences, and at the BIO convention among other conferences and outreach activities.

NIH agrees it is early in the implementation and recognizes that it takes time for new companies, which haven't participated before, to learn about the program, decide to apply, and prepare and submit SBIR applications. The NIH SBIR/STTR program office will track and monitor participation by VC-backed companies and its effect on the SBIR program over time.

9. The 2011 reauthorization legislation focused greatly on commercialization. One provision requires agencies to issue Phase III awards relating to technology, including sole source awards, to the SBIR and STTR award recipients that developed the technology. Has your agency made any such awards?

Answer: NIH does not fund or issue Phase III awards via the SBIR and STTR programs. NIH is not an acquisition agency, like the SBIR contracting agencies. Approximately 95 percent of the SBIR awards and 100 percent of the STTR awards are made in the form of grants-in-aid to small business concerns. The remaining ap-

proximately five percent of the SBIR awards are in the form of contracts. The technology funded by those contracts is rarely directly acquired by NIH. Beyond Phase I and II awards, NIH's intention is that these projects are supported in the private sector by venture capitalists, pharmaceutical, and biotechnology companies because of the significant amount of capital and development times necessary for clinical trials and federal regulatory approval. The overall goal of NIH's SBIR/STTR program is to commercialize the biomedical technology in the open market as a means to enhance health, lengthen life, and reduce illness and disability.